F. No. MED-16014(12)/1/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Devices Division)

FDA Bhawan, Kotla Road,
New Delhi – 110002
Dated: 06 JAN 2025

Notice

Subject: Updation of existing risk-based classification lists - Reg.

As per the notification vide S.O. 648(E) dated 11.02.2020, all Medical Devices are regulated under the Medical Devices Rules (MDR), 2017. In accordance to the Rule 4(3) of Chapter II of the MDR, 2017, the Central Licensing Authority needs to classify such medical devices as per risk-based approach.

In this regard, the existing classification lists of the following categories have been revisited and new entries have been added based on their classification as per the First Schedule (Part I) of the MDR, 2017 and the internationally-followed classification:

1. Interventional Radiology
2. Radiotherapy
3. Oncology
4. Class A (non-sterile and non-measuring) medical devices

The draft of the classification lists is annexed for finalization. All concerned associations/stakeholders are requested to forward their comments by filling the Google form (Link: https://docs.google.com/forms/d/1e-FFEU6wVU9nxgE-B40lJfeFdaMHxO_Y1jxUiQSq2sw/edit?pli=1) within 30 days from the date of publication of this draft.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To: All associations/stakeholders through the CDSCO website

Annexure I

(Reference File No.: MED-16014(12)/1/2024-eoffice)

CATEGORIES OF MEDICAL DEVICES FOR RISK-BASED CLASSIFICATION

S. No.	Categories of Medical Devices
1	Interventional Radiology
2	Radiotherapy
3	Oncology
4	Class A (non-sterile and non-measuring) medical devices

Note: All concerned associations/stakeholders are requested to forward their comments by filling the Google form at https://docs.google.com/forms/d/1e-FFEU6wVU9nxgE-B40lJfeFdaMHxO_Y1jxUiQSq2sw/edit?pli=1 within 30 days from the date of publication of this draft.

Name of Category:

Interventional Radiology

Total No. of Devices:

186

Category: Interventional Radiology

S. No.	Device name	Intended use	Risk Classification
1	Angiographic x-ray system	An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium.	**Class C**
2	Angiography contrast medium injection system, battery-powered	A battery-powered assembly of devices designed to inject contrast media through a small catheter and into the vascular system for angiographic procedures (e.g., examination of the coronary and renal arteries, and great vessels and vasculature of the heart, brain, abdominal organs, and extremities).	**Class C**
3	Angiography contrast medium injection system, line-powered, mobile/stationary	An assembly of devices designed to inject contrast media through a small catheter and into the vascular system for angiographic procedures (e.g., examination of the coronary and renal arteries, and great vessels and vasculature of the heart, brain, abdominal organs, and extremities). It consists of mains electricity (AC-powered) electromechanical injectors (electric motor connected to a jackscrew that moves a syringe piston) with syringes capable of delivering media with the pressure, flow range, and volume required for angiographic studies, and may be stationary or mobile (e.g., on a wheeled pedestal). Some types can synchronize media delivery with the electrocardiographic cycle and/or the x-ray generator.	**Class C**
4	Automatic radiographic film processor	An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.	**Class C**
5	Automatic-aperture-control diagnostic x-ray system collimator	A standard, diagnostic x-ray beam-limiting and shaping device that includes an automatically controlled motorized shutter mechanism. It is designed to adjust the shutters so that the x-ray beam shape matches the size of the film cassette in the holder and is attached to the beam exit port of a diagnostic x-ray system tube housing assembly. It is used to limit the effects of scattered radiation on image quality and to provide patient protection by eliminating exposure to non-target body areas.	**Class B**
6	Axial length measuring ultrasound system	An ophthalmic device that uses ultrasound technology to measure axial length of the eye (distance along the axis of the eye between the anterior corneal surface and the anterior retinal surface).	**Class B**

S. No.	Device name	Intended use	Risk Classification
7	Basic diagnostic x-ray system table, non-powered	A non-powered table that is a component of a basic diagnostic x-ray system designed to position and support a patient during a variety of routine/planar or speciality diagnostic procedures requiring the use of a diagnostic x-ray system; it is not a planar tomography nor computed tomography (CT) table. It is not intended for use during interventional radiology/surgery.	**Class B**
8	Basic diagnostic x-ray system table, powered	A powered/programmable table that is a component of a basic diagnostic x-ray system designed to position and support a patient during a variety of routine/planar or speciality diagnostic procedures requiring the use of a diagnostic x-ray system; it is not a planar tomography nor computed tomography (CT) table. It is not intended for use during interventional radiology/surgery.	**Class B**
9	Basic/General-purpose diagnostic x-ray system, mobile/stationary /portable	An assembly of devices that comprise an analogue general-purpose mobile diagnostic x-ray system used in a variety of routine x-ray imaging applications. It is typically an x-ray film based system using analogue or analogue-to-digital techniques for image capture and display. It is commonly used for bedside imaging and for interventional and intraoperative imaging.	**Class C**
10	Bladder ultrasound imaging transducer	An ultrasound imaging transducer assembly specifically designed to be positioned within the bladder either manually or under endoscopic guidance that steers, focuses, and detects the ultrasound beam and resulting echoes either mechanically or electronically.	**Class B**
11	Bladder volume ultrasound imaging system	An assembly of portable, battery-powered devices designed for the extracorporeal ultrasound measurement of the male or female urinary bladder volume. It typically consists of an electronic measuring and imaging display unit with a connected ultrasound transducer which together reproduce digitized data of the bladder, typically bladder volume and post-void residual (PVR), and images. It will generate ultrasound pulses, direct them to the target area, detect the ultrasound echoes, and process the resulting information to produce and display static or dynamic three-dimensional (3-D) data/images. It is used in the diagnosis of urinary retention and postoperative urinary retention (POUR).	**Class B**

S. No.	Device name	Intended use	Risk Classification
12	Blood flowmeter catheter, Doppler	A flexible tube intended to be inserted into the lumen of a blood vessel to determine blood-flow velocity by measuring the ultrasonic frequency shift between transmitted and reflected signals (Doppler principle).	**Class C**
13	Body-orifice ultrasound imaging transducer cover	A sheath intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gliding creams) and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used in natural body orifices (e.g., vagina, rectum, oesophagus) during an ultrasound examination; it has no additional functionality.	**Class B**
14	Body-orifice ultrasound imaging transducer cover, image-enhancement	A sheath containing an extraluminal pocket/balloon portion intended to cover an ultrasound imaging system transducer (probe) used in natural body orifices (e.g., vagina, rectum), to both protect the transducer and improve image quality. The balloon portion is intended to, when filled with an aqueous solution (e.g., saline), displace air and provide an adjustable interface between the transducer and the anatomy of interest (e.g., prostate) to improve imaging.	**Class B**
15	Bone densitometer	A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues.	**Class C**
16	Bone sonometer	A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk.	**Class B**
17	Cardiovascular MRI system, Permanent magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a permanent magnet, and can be stationary, mobile, or portable. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.	**Class C**

S. No.	Device name	Intended use	Risk Classification
18	Cardiovascular MRI system, resistive magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a resistive magnet and is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.	**Class C**
19	Cardiovascular MRI system, Superconducting magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The device is typically equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.	**Class C**
20	Cardiovascular ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for extracorporeal and/or intracorporeal (endosonography or endoscopic) imaging procedures involving the heart and blood vessels. Included are software packages that support a variety of static or real-time cardiac specific imaging applications used to diagnose anatomical defects of the heart, determine blood flow characteristics and functional/anatomical problems associated with myocardial infarction. It is used to generate ultrasound pulses, direct them to a target area, detect the echoes, and process the resulting information to produce and display static or dynamic two or three-dimensional (3-D) images. May be used in intraoperative surgical planning.	**Class C**
21	Cephalometric digital X-ray sensor	A sensor for a digital X-ray image processing system combined with a diagnostic X-ray system designed for visualization and size measurement of the human head (skull) using radiation. The sensor consists of the charge coupled devices (CCDs) and contains a sensor driving circuit and signal processing circuit	**Class C**
22	Cine or spot fluorographic x-ray camera	A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an imageintensifier	**Class C**

S. No.	Device name	Intended use	Risk Classification
23	Computed radiography digital imaging scanner	A device/device assembly designed to be used with an analogue x-ray system to capture radiographic images and then generate digital x-ray images from them as part of a two-step process (computed radiography) for image viewing, storage, or hard-copy printing; it is not dedicated to dental use. It consists of an image reader/scanner and may also include an exposure unit with imaging receptor (e.g., a cassette containing a plate), or additional supportive hardware (e.g., a printer).	**Class B**
24	Computer system for ultrasound imaging system	A mainframe computer, a personal computer (PC) or a PC-based platform, and related hardware, software and operating system software dedicated used for controlling and monitoring performance of a diagnostic ultrasound system and related image processing, display and analytical functions.	**Class B**
25	Contrast medium conservation system (Contrast management system)	An assembly of electromechanical devices that controls the amount of contrast agent supplied to the syringe/injector portion of the contrast medium injector system. It is designed to optimise the use of injectible contrast agents in order to prevent unnecessary waste of contrast media during and/or between patient procedures.	**Class B**
26	Contrast medium injection system administration set	A collection of noninvasive devices designed to conduct fluids between a contrast medium injection system and a patient catheter for the delivery of a contrast medium and/or saline solution to a patient undergoing a diagnostic imaging procedure. It consists of tubing with switches/valves and connectors to syringes/fluid/contrast medium injection system, and possibly a pressure transducer. This is a disposable device.	**Class B**
27	Contrast medium injection system control unit	A mains electricity (AC-powered) electronic device that may be a component of a contrast medium injector system and designed to initiate and terminate the operation of a contrast medium injection procedure from a remote location (e.g., the shielded operators control room).	**Class C**

S. No.	Device name	Intended use	Risk Classification
28	Contrast medium injection system hand controller kit	A collection of non-powered devices designed to be used and interact with a contrast medium injection system for the administration of a contrast medium or saline solution to a patient undergoing a diagnostic imaging procedure. It consists of a high pressure line, a high pressure stopcock, and a hand-held manual controller used to stop and start the contrast medium injection system instantaneously.	**Class C**
29	Contrast medium injection system syringe	A component of a contrast medium injection system for the administration of a contrast medium or saline solution to a patient undergoing a diagnostic imaging procedure. It is primarily an exchangeable plunger-in-barrel chamber for the medium/solution; the movement of the plunger (piston) is controlled by the contrast medium/solution injector. This is a reusable device.	**Class B**
30	Coronary optical coherence tomography system	An assembly of optical and computer-based devices that use a broad-bandwidth light beam for optical coherence tomography (OCT) to provide high-resolution images (e.g., 5 to 40 microns) of the coronary intravasculature. The system includes an optical-imaging catheter which is connected to the console for transmission of the images from the intravascular site. The system may be used during interventional cardiology, radiology, or diagnostic angiography.	**Class C**
31	Coronary optical coherence tomography system catheter	A sterile flexible tube with an extremely fine working end that houses an optical fibre and imaging lens intended to be transcutaneously introduced into the coronary vasculature to perform coronary optical coherence tomography (OCT). The proximal end of the device connects to a coronary OCT console for the transmission of high-resolution images (e.g., 5 to 40 micron) of the coronary intravasculature.	**Class D**
32	CT contrast medium injection system, stationary/mobile	An assembly of devices designed to inject contrast media through a small catheter and into the vascular system for computed tomography (CT) procedures (e.g., spine, head, gastrointestinal, or vascular diagnostic procedures using CT scanning). The system may synchronize media delivery with the x-ray generator during CT scanning.	**Class C**

S. No.	Device name	Intended use	Risk Classification
33	Dental computed radiography digital imaging scanner	A device/device assembly dedicated to dental use and designed to be used with an analogue dental x-ray system to capture radiographic images and then generate digital x-ray images from them as part of a two-step process (computed radiography) for image viewing, storage, or hard-copy printing. It consists of an image reader/scanner and may also include an exposure unit with imaging receptor (e.g., a cassette containing a plate), or additional supportive hardware (e.g., a printer).	**Class B**
34	Dental digital X-ray imaging sensor	A digital dental X-ray sensor used in the oral cavity, in combination with a general-purpose dental X-ray imaging device. The sensor consists of a CCD or other components, and comprises a sensor drive circuit and a signal processing circuit.	**Class B**
35	Dental x-ray film, screen	A screen x-ray film specifically sized and designed for use with dental x-ray systems. It is designed to be sensitive primarily to the wavelengths of light emitted from an image intensifying screen. May be used endorally/extraorally.	**Class B**
36	Diagnostic ultrasonic transducer	A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices.	**Class B**
37	Diagnostic x-ray beam-limiting device	A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic x-ray field by limiting the size of the primary x-ray beam.	**Class C**
38	Diagnostic x-ray digital imaging conversion system	An assembly of medical devices designed to convert an existing analogue x-ray system to digital (i.e., retrofit) through the acquisition and processing of digital images using existing analogue x-ray system components. As a system it consists of both: 1) a filmless cassette-size digital detector (e.g., indirect flat panel detector); and 2) additional processing/viewing hardware [e.g., a central processing unit (CPU) with integrated software and a monitor]. It does not contain the controls for the direct operation of an x-ray imaging system.	**Class B**

S. No.	Device name	Intended use	Risk Classification
39	Diagnostic x-ray digital imaging system workstation	A freestanding component of an x-ray-based diagnostic digital imaging assembly intended to associate X-ray/CT/fluoroscopic images with patient and exam information, apply images processing to facilitate diagnosis, display the images, and output the resulting image and exam data for further display, distribution, or archiving. It may be intended to be integrated as part of a radiology picture archiving and communication system (PACS) and does not have controls for direct operation of the imaging system.	**Class B**
40	Diagnostic x-ray high voltage generator	A diagnostic x-ray high voltage generator is a device that is intended to supply and control the voltage and electrical energy provided to a diagnostic x-ray tube for medical purposes.	**Class B**
41	Diagnostic x-ray tube housing assembly	A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes.	**Class B**
42	Digital angiographic x-ray system, mobile/stationary /portable	An assembly of devices intended to visualize and optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses digital technology for real-time image capture, display, and manipulation, and typically may have a radiographic function in addition to fluoroscopic function.	**Class C**
43	Digital basic diagnostic x-ray system, mobile/portable/stationary	An assembly of devices that comprise a digital general-purpose mobile diagnostic x-ray system used in a variety of routine planar x-ray imaging applications. It uses digital techniques for image capture, display and manipulation. It is commonly used for bedside imaging and for interventional and intraoperative imaging.	**Class C**
44	Digital cephalometric x-ray system	An x-ray system designed to generate and control x-ray beams and to record the absorption patterns of x-rays passing through a patient's head (skull). It is used for: 1) radiographic visualization and measurement of the dimensions of the human head, e.g., abnormal structures of the skull; 2) orthodontic assessment of the relationship of the teeth to the jaws and the jaws to the rest of the facial skeleton; 3) assessment airway and other soft tissue structures.	**Class C**

S. No.	Device name	Intended use	Risk Classification
45	Digital general-purpose fluoroscopic x-ray system, mobile/portable/stationary	A general-purpose diagnostic fluoroscopic x-ray system that uses a C-arm and digital techniques for image capture, display and manipulation and is designed to be used in a variety of general-purpose applications requiring real-time fluoroscopic imaging capabilities. It is also intended to optimize the capability of users to visually and quantitatively evaluate the anatomy and physiological function of various targeted body areas in real-time. It is frequently used in conjunction with an ingested or injected x-ray contrast medium. Images can be both real-time and delayed formats.	**Class C**
46	Digital imaging cassette/storage phosphor screen, basic diagnostic x-ray (CR cassette)	A device that includes both a digital imaging cassette and a phosphor plate (also known as screen) intended to receive radiation by a diagnostic x-ray system, to record a patient radiation pattern during a non-dental procedure. The device is then transferred, with the cassette shielding the plate from environmental light, to a computed radiography (CR) scanner for insertion to produce the digital image of the patient.	**Class B**
47	Digital intraoral dental x-ray system, mobile/portable/stationary/hand-held	A diagnostic dental x-ray system designed to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. The data is either from analogue-to-digital conversion techniques imaging or by digital imaging.	**Class C**
48	Digital mammographic x-ray system, mobile/stationary /portable	An assembly of devices specifically designed to be installed permanently and intended to compress and image the breast. It is primarily used to optimize the capability of users to visually evaluate x-ray film images representing the anatomy and function of blood and lymphatic vessels within the human breast. It may be used for breast cancer screening and in conjunction with the placement of biopsy markers and stereotactic biopsy and lesion localization equipment requiring x-ray guidance.	**Class C**

S. No.	Device name	Intended use	Risk Classification
49	Digital panoramic/tomographic dental x-ray system (OPG)	A diagnostic digital dental x-ray system designed for permanent fixture in one location with an extraoral x-ray sensor and source intended to generate and control x-ray beams used in advanced dental imaging applications involving the teeth, jaw, oral cavity, sinus, and/or other maxillofacial structures.	**Class C**
50	Digital uro-gynaecological fluoroscopic x-ray system	A diagnostic x-ray system with real-time fluoroscopic capabilities specifically designed for use in urological and/or gynaecological surgical and interventional procedures requiring real-time visualization of the pelvic area.	**Class C**
51	Doppler blood-flow measurement ultrasound system	A portable or stationary ultrasonic device (invasive or noninvasive) that does not produce 2-dimensional or 3-dimensional images, and is intended to be used for determining various blood-flow related parameters of the heart, artery, or vein. The device is used to output audible data, or display the Doppler shift as a function of time.	**Class B**
52	Electrostatic x-ray imaging system	An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x- radiation into an electrostatic image and, subsequently, into a visible image.	**Class C**
53	Emission computed tomography system	An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data	**Class C**
54	Extracorporeal ultrasound imaging transducer, hand-held (ultrasound probe)	A hand-held noninvasive component of an ultrasound imaging assembly designed to be moved over the intact surface of a patient's body, typically with a coupling gel, during a variety of extracorporeal ultrasound imaging procedures (non-dedicated). it converts electric voltages into ultrasound which it transmits, detects resulting echoes, and transmits a proportional signal/data to an ultrasound system controller for image processing and display. This is a reusable device.	**Class B**
55	Extremity MRI system, permanent magnet	A diagnostic magnetic resonance imaging (MRI) system employing permanent magnet technology specifically designed to image only the head and neck or limbs.	**Class B**

S. No.	Device name	Intended use	Risk Classification
56	Extremity MRI system, superconducting magnet	A diagnostic magnetic resonance imaging (MRI) system employing superconducting magnet technology specifically designed to image only the head and neck or limbs.	**Class B**
57	Flat panel radiography and fluoroscopy system	A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray flat panel detector, and digital output signals are supplied to an image processing device to receive digital images. If necessary, image processing technology including gamma correction and edge enhancement are applied to digital images. Image data are either recorded on the media, or output to a server or other external devices for recording.	**Class C**
58	Flexible endoscopic ultrasound imaging transducer	A flexible, ultrasound imaging transducer assembly designed to be to be inserted through the working channel of an appropriate flexible endoscope and positioned within the gastrointestinal, respiratory or urinary tract, (i.e., application is not specific to any particular anatomy) to transmit a signal/data to another device for display. This is a reusable device.	**Class B**
59	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy.	**Class B**
60	Flexible ultrasound colonoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the entire colon [lower gastrointestinal (GI) tract]. It is inserted through the anus during colonoscopy.	**Class B**
61	Flexible ultrasound duodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the duodenum (the first part of the small intestine). It is inserted into the body through the mouth during duodenoscopy.	**Class B**
62	Flexible ultrasound gastroduodenoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination and treatment of the upper gastrointestinal (GI) tract [oesophagus, stomach, and duodenum (the first part of the small intestine), including the pancreas and the bile duct]. It is inserted into the body through the mouth during gastroduodenoscopy.	**Class B**

S. No.	Device name	Intended use	Risk Classification
63	Flexible ultrasound laparoscope	An endoscope with a flexible inserted portion, combined with an ultrasound probe, intended for the visual examination, treatment, and ultrasonic imaging of the abdominal/retroperitoneal cavity and its organs. It is inserted through an incision made in the abdominal wall (routinely just below the umbilicus) during laparoscopy.	**Class B**
64	Fluorescent scanner	A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays.	**Class C**
65	Foetal cardiac monitor	A mains electricity (AC-powered) device designed to detect, measure, and display foetal heart activity during the perinatal period.	**Class C**
66	Foetal Doppler system	A portable, hand-held, battery-powered device assembly consisting of a measuring and display unit and an attached probe or interchangeable probes designed to noninvasively detect foetal heart beats using ultrasound/Doppler technology. The heart beats are typically conveyed audibly via the measuring/display unit and attached probe which is applied to the surface of the pregnant woman's abdomen. The device aids in determining foetal viability.	**Class C**
67	Full-body MRI system, permanent magnet	A general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body. It includes a permanent magnet assembly.	**Class C**
68	Full-body MRI system, resistive magnet	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). It includes a resistive magnet assembly.	**Class C**
69	Full-body MRI system, superconducting magnet	A diagnostic general-purpose magnetic resonance imaging (MRI) system designed to scan any targeted area of the body (full-body imaging). This system includes a superconducting magnet assembly.	**Class C**
70	General-purpose ultrasound imaging system	A stationary or mobile (e.g., on wheels) assembly of devices designed to collect, display, and analyse ultrasound images during a variety of extracorporeal and/or intracorporeal (endosonography or endoscopic) ultrasound imaging procedures (e.g., cardiac, OB/GYN, endoscopy, breast, prostate, vascular, and intra-surgical imaging).	**Class B**

S. No.	Device name	Intended use	Risk Classification
71	General-purpose fluoroscopic x-ray system, mobile/portable/stationary	A general-purpose, analog diagnostic fluoroscopic x-ray system designed to be used in a variety of general-purpose applications requiring real-time fluoroscopic imaging capabilities. It is frequently used in conjunction with an ingested or injected x-ray contrast medium. Images can be both real-time and delayed formats.	**Class C**
72	Grid for MRI (needle guide positioner)	A grid used for position the puncture site etc. when biopsying under the magnetic resonance imaging (MRI) guide.	**Class A**
73	Hand-held intraoral dental x-ray system	A diagnostic dental x-ray system designed to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. The sensor is placed in the mouth, the purpose being to visualize a limited region in detail. The data is either from analogue imaging and digitized afterwards or by digital imaging.	**Class C**
74	Hand-held ultrasound imaging system, body-surface	A battery-powered, hand-held device/device assembly designed to be placed over the external body surface for collection, display, and analysis of ultrasound information during a variety of ultrasound imaging procedures (i.e., non-dedicated); it may in addition be intended to be used with a sterile cover for intraoperative imaging. It consists of a flat- or concave-lensed ultrasound transducer and includes an integrated image processing system; it may include an integrated display or be intended to wirelessly transmit images to an off-the-shelf device (e.g., smartphone, tablet) with dedicated software installed. It is not designed to be inserted into body orifices.	**Class B**
75	Hand-held ultrasound imaging system, rectal/vaginal	A battery-powered, hand-held device/device assembly designed to be inserted in vaginal/rectal cavity for collection, display, and analysis of ultrasound information during a variety of ultrasound imaging procedures (i.e., non-dedicated); it may in addition be intended to be used with a sterile cover for intraoperative imaging.	**Class B**

S. No.	Device name	Intended use	Risk Classification
76	Hand-held-detector nuclear medicine system	An assembly of diagnostic devices comprising a hand-held, non-imaging system designed primarily to detect, record, quantify and analyse various radioactive emissions (gamma, alpha, beta) of injected or ingested radiopharmaceuticals, radiation emitting devices, or other materials. It is frequently used in the monitoring and detection of deep vein thrombosis (DVT), in surgical procedures requiring radionuclide localization and in some radiolabeled monoclonal antibody applications.	**Class B**
77	Head/extremity imaging MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using a resistive magnet.	**Class C**
78	Hepatic ultrasound elastography system	An assembly of mains electricity (AC-powered) devices, which may include rechargeable batteries, designed to measure liver stiffness/ultrasonic attenuation of tissues based on transient elastography for the evaluation/diagnosis of hepatic disease (e.g., liver fibrosis/steatosis); it may additionally be intended to measure spleen stiffness as an adjunct evaluation. It is typically used during diagnosis of chronic liver conditions such as viral hepatits, alcoholic hepatitis, and biliary disease, or for post-transplant evaluation.	**Class B**
79	Image-intensified fluoroscopic x-ray system	An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification.	**Class C**
80	Indirect flat panel x-ray detector	An electrically-powered, cassette-like device intended to be used as part of an x-ray system to detect x-ray images following exposure, and create a digital signal; it is not dedicated to imaging of a specific anatomy. It includes two types of transducing technology (i.e., indirect): a scintillator [e.g. caesium iodide (CsI)] screen converts x-ray energy into light, followed by the conversion of light into a digital signal by photodiode array. The image data can be sent to an appropriate processing unit through a wired or wireless connection (e.g., Wi-Fi). It may be used in place of a fixed detector in x-ray imaging systems, e.g., as part of a digital imaging conversion system.	**Class B**

S. No.	Device name	Intended use	Risk Classification
81	Integrated ultrasound/electrocardiograph/ stethoscope unit	An electrically-powered modular device intended for general medical examination using ultrasound, electrocardiograph (ECG) and auscultation modalities, with a user interface that enables synchronized data display and recording. It consists of a multi-purpose transducer designed for transmitting/receiving ultrasound and sensing sound signals, to which an ECG lead assembly can be attached, and a connected image display monitor (e.g., tablet) with dedicated software; in addition to the integrated electronic stethoscope, it may also allow connection of a stethoscope headset for the user to directly hear sounds.	**Class C**
82	Intracardiac ultrasound imaging catheter, steerable, single-use	A steerable, flexible tube with an ultrasonic phased-array imaging transducer at its distal tip designed for intracardiac echocardiography to enable intracardiac and possibly great vessel (e.g., pulmonary artery) visualization for the assessment of cardiac anatomy and physiology, and visualization of other devices in the heart; it is not intended for peripheral vascular or coronary artery insertion/imaging. It is introduced percutaneously, and includes controls to allow it to be manoeuvred (steerable). It is connected to a compatible ultrasound system for transmission and display of the images. This is a single-use device.	**Class D**
83	Intracorporal ultrasound transducer contouring attachment	Intended to be used with a hand-held ultrasound imaging system transducer to provide means to replace the position of a needle guide.	**Class B**
84	Intracorporeal central nervous system ultrasound transducer/probe	An ultrasonic probe used temporarily in central nervous system surgery. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take local images during surgery. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning.	**Class D**

S. No.	Device name	Intended use	Risk Classification
85	Intraoperative ultrasound imaging transducer cover	A sterile sheath intended to be used as a physical barrier for protection against the effects of environmental exposure (e.g., body fluids, gels) and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used intraoperatively, e.g., on internal organs, during an ultrasound examination. This is a single-use device.	**Class B**
86	Intraoral dental x-ray system, mobile/portable/stationary/hand-held	A diagnostic dental x-ray system designed to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures.	**Class C**
87	Intravascular optical coherencetomography catheter	A catheter and a guide wire used to observe a cross section of blood vessels using an optical fiber by light. For instance, optical coherence tomography visualizes internal microscopic structure of the tissues without physical invasion of the outer protective layers. This utilizes the nature of light that penetrates and is reflected at various degrees according to the type of the tissue.	**Class D**
88	Intravascular ultrasound imaging catheter, non-steerable	A flexible, non-steerable tube with an ultrasound imaging transducer enclosed in a fluid-resistant or waterproof acoustically- and electrically-insulated housing, designed for insertion into the vascular system (i.e., peripheral vascular system, coronary artery) by an operator; it is not intended for intracardial insertion/imaging. Also known as a vascular ultrasound transducer, it includes either a single or an array of transducer element(s) (piezoelectric, active, or crystal).	**Class C**
89	Invasive vascular ultrasound system	A mains electricity (AC-powered) device assembly designed to invasively locate and assess the extent of vascular flow restriction (e.g., clots, stenosis, mechanical damage) using ultrasound/Doppler/transit time technology during procedures involving vascular surgery. It may also provide additional measurements (e.g., blood pressure, vascular resistance). It consists of a mobile (on wheels) control unit with graphical user-interface, typically placed outside the sterile field; and an attached, reusable, sterilizable probe intended to be used within the body (invasive) but not within the lumen of the blood vessel.	**Class C**

S. No.	Device name	Intended use	Risk Classification
90	Invasive vascular ultrasound system probe	A hand-operated component of an invasive vascular ultrasound system intended to be used perioperatively/intraoperatively to measure the flow of blood in an isolated blood vessel, by being applied to the outside of the vessel, using ultrasonic/Doppler/transit time technology. It may also be used for cross-sectional visualization/imaging. This is a reusable device.	**Class C**
91	Limited view field X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system equipped with a gantry designed exclusively for taking images of the area from the head to the neck or the extremities. The system is designed to have at least 1 fixed circular arrangement of multiple X-ray tubes and detectors, or designed to have an assembly where single or multiple X-ray tube(s) and detector(s) rotate around an axis at high speed within the area that the gantry can take images. Using this system, 2D or 3D images are produced. In addition, spiral CT and special radiography can be performed at multiple angles set relative to the position of the body.	**Class C**
92	Mammographic biopsy x-ray table, powered	A powered/programmable x-ray mammography table with electronic positional controls specifically designed to position and support a patient during breast imaging examinations usually in conjunction with breast biopsy. It is made of radiolucent materials with low x-ray attenuation coefficients and typically has special openings or attachments to facilitate breast imaging.	**Class B**
93	Mammographic MRI system, Permanent magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a permanent magnet, and can be stationary, mobile, or portable. The MR device for mammography is typically equipped with a dedicated patient support bed specifically for the purpose of controlling the positioning of the patient's body to optimize visualization of the breast.	**Class C**
94	Mammographic MRI system, Resistive magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a resistive magnet, and can be stationary, mobile, or portable. The MR device for mammography is typically equipped with a dedicated patient support bed for the purpose of controlling the	**Class C**

S. No.	Device name	Intended use	Risk Classification
		positioning of the patient's body to optimize visualization of the breast.	
95	Mammographic MRI system, Superconducting magnet	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The MRI device for mammography is typically equipped with a dedicated patient support bed for the purpose of controlling the positioning of the patient's body to optimize visualization of the breast.	**Class C**
96	Mammographic stereotactic biopsy system	An assembly of devices intended to be used in conjunction with mammography to insert biopsy devices, typically designated needles, into a breast in order to extract a biopsy of a suspect tumour for diagnostic purposes. It consists of a biopsy unit with needle guides, needles, an examination table, and an integral computer for communicating lesion coordinates. It may be a standalone unit or a unit that mounts onto an existing mammographic unit.	**Class B**
97	Mammographic x-ray system (portable/mobile/ stationary)	A mammographic x-ray system is a device intended to be used to produce radiographs of the breast for diagnostic purposes. It may be used intraoperatively.	**Class C**
98	Mammographic x-ray system stereotactic unit	A device that can only fulfil its purpose when used together with and enhance the function of a diagnostic mammographic x-ray system. It is used to take two pictures of a breast from two different angles. On the basis of this stereoscopic picture set, it is possible to determine the exact position of a lesion in the breast and a cytological sample of this will be taken. This device or technique may be built-in to some diagnostic x-ray systems for mammography.	**Class B**

S. No.	Device name	Intended use	Risk Classification
99	Mammographic x-ray system, mobile/stationary /portable	An assembly of devices specifically designed to be installed permanently and intended to compress and image the breast. It is primarily used to optimize the capability of users to visually evaluate x-ray film images representing the anatomy and function of blood and lymphatic vessels within the human breast. It may be used for breast cancer screening and in conjunction with the placement of biopsy markers and stereotactic biopsy and lesion localization equipment requiring x-ray guidance.	**Class C**
100	Manual contrast medium injection system	An assembly of devices designed for the manual-only injection of contrast media into the blood or lymphatic vessels of a patient for a diagnostic imaging procedure; it enables the operator to manually control the volume and rate of contrast media administered under pressure. The system typically consists of a graduated injection syringe, a manifold with multiple stopcocks, and a pressure transducer system used by the operator to monitor catheter-tip pressure.	**Class B**
101	Medical image analyzer/Medical image interpretive application software	Medical image analyzers, including computer-assisted/aided detection (CADe) devices for mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection, are intended to identify, mark, highlight, or in any other manner direct the clinicians' attention to portions of a radiology image that may reveal abnormalities during interpretation of patient radiology images by the clinicians. This device incorporates pattern recognition and data analysis capabilities and operates on previously acquired medical images. This device is not intended to replace the review by a qualified radiologist, and is not intended to be used for triage, or to recommend diagnosis.	**Class B**
102	Medical x-ray film, screen	A screen x-ray film specifically designed for medical diagnostic imaging applications. It is sensitive primarily to wavelengths of light emitted from an image intensifying screen or other visible light source. This film is not limited to use with x-ray imaging systems but can also be used in a variety of diagnostic imaging modalities using image intensifier technology or matrix formatters to output images, e.g., nuclear medicine or ultrasound.	**Class B**

S. No.	Device name	Intended use	Risk Classification
103	MR/CT roadmap (interpretive software)	A stand alone software that allows the synchronization of live fluoroscopy images with previously acquired MRA/CTA datasets. This may be used as an aid in applications such as image-guided surgeries, calibrating the contrast medium doses, and needle guidance.	**Class C**
104	MRI contrast medium injection system, mobile/stationary	An assembly of devices designed to inject contrast media through a small catheter and into the vascular system for magnetic resonance imaging (MRI) procedures (e.g., spine, head, gastrointestinal, or vascular diagnostic procedures using MRI). It may interface with the MRI system or a monitoring device to control timing of contrast injections; it is made entirely of non-ferromagnetically active materials for MRI compatiblity.	**Class C**
105	MRI image interpretive software	An interpretive software program intended to be used to analyse magnetic resonance imaging (MRI) data (e.g., prostate MRI) to detect and localize suspected abnormalities and sometimes provide results as clinically relevant tags; it may additionally be intended for three-dimensional (3-D) model creation slice-based images (segmentation). It typically utilizes artificial intelligence (AI) and deep learning techniques, and may be compatible with radiology information systems, data formats, and medical imaging software programs [e.g., picture archiving and communication system (PACS), digital imaging and communications in medicine (DICOM) format].	**Class C**
106	MRI planner (radiotherapy planning application software)	It is a stand alone software product intended to enable a completely MRI-only workflow in radiotherapy planning. It achieves this by analyzing a dedicated MR image and generating a synthetic CT image that can replace the conventional CT in the treatment planning process. In addition, the software may also performs automated contouring of risk organs in certain anatomies.	**Class C**
107	MRI radio frequency coil	This radio frequency coil is intended to act as a transmitter, receiver, or both a transmitter and receiver of RF pulses necessary for diagnostic magnetic resonance imaging (MRI) procedures. It is intended to be used to enhance image resolution by improving signal to noise characteristics.	**Class B**

S. No.	Device name	Intended use	Risk Classification
108	MRI system application program software	It is a standalone software application that is intended to be used for viewing, post-processing and quantitative evaluation of magnetic resonance (MR) images for applications such as quantitative cardiovascular computed tomography (CT) evaluation, determination of the triglyceride fat fraction in magnetic resonance images of the liver, multi slice and gradient echo image analysis, etc. It does not drive MRI systems.	**Class C**
109	MRI system synchronizer	A physiological monitoring unit used as a component of a diagnostic magnetic resonance imaging (MRI) system, that produces a signal which enables image formation or data collection to be synchronized with a specific measurable physiological parameter, e.g., the beginning of a patient's respiratory or cardiac cycle. It is primarily used for the purpose of artifact reduction or enhancement of signal-to-noise ratios in various real-time or dynamic MRI applications.	**Class B**
110	MRI system table, powered	A powered/programmable table designed with electronic and/or software controls to position and support a patient during magnetic resonance imaging (MRI) examinations. It is made with ferromagnetically inactive materials and may have a detachable table top, equipment supports, physiological monitors, mattresses, alarms and a patient positioning system (PPS).	**Class B**
111	MRI system workstation	A standalone image-processing workstation that is designed to be networked with one or more magnetic resonance imaging (MRI) systems. The workstation may have any type of hardware, or any type of configuration. It is not intended to control or directly manipulate the diagnostic imaging device. The device allows data transfer either on-line or off-line, and is typically situated away from the MRI operator console. It is intended to process MRI images and provide valuable information that allow decision making, evaluation or diagnosis of the patient's pathologic conditions.	**Class B**

S. No.	Device name	Intended use	Risk Classification
112	MRI-patient physiologic monitoring system	A mobile assembly of devices designed for continuous assessment of several vital physiologic parameters (e.g., ECG, blood pressure, heart rate, temperature, cardiac output, apnoea, and respiratory/anaesthetic gas concentrations) of infant to adult intensive care patients during a magnetic resonance imaging (MRI) procedure.	**Class C**
113	Multi-modality diagnostic x-ray system (full body CT/fluoroscopic x-ray system)	An assembly of diagnostic x-ray devices intended to acquire, display and process images from any part of the body (full-body) incorporating the techniques of more than one x-ray imaging modality, typically including real-time fluoroscopy, two-dimensional (2D) radiography, and computed tomography (CT); it is not a single-modality system.	**Class C**
114	Neurosurgical ultrasound navigation system application software	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a neurosurgical ultrasound (US) navigation system.	**Class C**
115	Neurosurgical ultrasound navigation system optical tracking unit	A component of a neurosurgical ultrasound (US) navigation system used to track the position of all the localizers/spatial markers during intraoperative imaging and to supply the US system with valid positional data. It typically uses equidistant-placed cameras using infrared (IR) light to measure the position/placement of the reflective spheres attached to the localizers or spatial marker holders.	**Class B**
116	Nonfetal ultrasonic monitor	A nonfetal ultrasonic monitor is a device that projects a continuous high frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion.	**Class B**
117	Non-image-intensified fluoroscopic x-ray system	A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of X-ray radiation into a visible image.	**Class C**

S. No.	Device name	Intended use	Risk Classification
118	Noninvasive vascular ultrasound probe	A hand-operated component of a vascular ultrasound system intended to be used to measure the flow of blood noninvasively by measuring flow in underlying vasculature from the body surface pre-/post-operatively, using ultrasonic/Doppler/transit time technology. It may also be used for cross-sectional visualization/imaging.	**Class B**
119	Noninvasive vascular ultrasound system	An electrically-powered device assembly consisting of a control unit and an attached probe or interchangeable probes, designed to noninvasively locate and assess the extent of vascular (venous and arterial) flow restriction (e.g., clots, stenosis, mechanical damage) by measuring blood flow rate using ultrasound/Doppler/transit time technology. It may also be used to detect the foetal heartbeat.	**Class C**
120	Nuclear electrocardiogram synchronizer/Nuclear medicine system synchronizer	A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images.	**Class B**
121	Nuclear medicine data processing system	A data processing system specifically dedicated for nuclear medicine. The system is used for various types of filter processing, image display, clinical analysis, management of image storage, etc. The system may have a control system for directly operating a diagnostic imaging unit. This system can deliver or receive data online or offline, and has a configuration that can provide functions such as processing, manipulating, and displaying a patient's images and information collected with the nuclear medicine scan.	**Class C**
122	Nuclear medicine system workstation	A standalone imaging workstation specifically designed to create network connection with one or more nuclear imaging devices, such as gamma camera, PET device, and SPECT device. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). It differs from an operator console in that the workstation does not have controls for the direct manipulation of the imaging device.	**Class B**

S. No.	Device name	Intended use	Risk Classification
123	Nuclear sealed source for absorption compensation	A sealed radioisotope equipped dedicated for the correction of absorption of radiation from a diagnostic radioisotope by organs and tissues to improve quantitative capability of diagnostic imaging of the nuclear imaging system (PET or SPECT devices), thereby improving accuracy of diagnosis.	**Class B**
124	Nuclear tomography system/nuclear medicine system	A nuclear tomography/medicine system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes.	**Class C**
125	Nuclear whole body scanner	A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide- aperture detector whose position moves in one direction with respect to the patient.	**Class C**
126	Oesophageal ultrasound imaging transducer (oesophagal endosonography probe/transducer)	An ultrasound imaging transducer assembly enclosed in a fluid-resistant, acoustically- and electrically-insulated housing, designed to be inserted and positioned in the oesophagus to obtain ultrasound images of the heart and/or to navigate devices requiring ultrasound guidance and placement (e.g., endoscopy equipment or needle biopsy equipment). It is composed of either a single transducer element or an array of transducer elements, i.e., piezoelectric element(s), active element(s), or crystal(s), and associated damping, backing, and matching layer materials. It is reusable.	**Class B**
127	Ophthalmic ultrasound imaging transducer	An ultrasound imaging transducer that is a hand-held device moved over the intact surface of a patient's eye during imaging applications involving the examination of the lens. It may include single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. This group of devices typically includes ultrasound imaging transducers used with A-mode scanning capabilities. This is a reusable device.	**Class B**

S. No.	Device name	Intended use	Risk Classification
128	Optical coherence tomography (OCT) imaging system	An OCT (optical coherence tomography) diagnostic imaging system which diagnostically represents the images of tissue characteristics and shapes of various sites (e.g., heart, blood vessel, abdomen, lung) using near-infrared rays, without the need to obtain tissues surgically. This system may or may not contain a software package that supports the taking of both still and real-time images, and is used to diagnose anatomic abnormalities in tissues and to examine functional and anatomic features.	**Class C**
129	Optoacoustic/ultrasound imaging system	A mobile assembly of electrically-powered devices intended for imaging and analysis of soft-tissue and soft-tissue vasculature using combined optoacoustic (photoacoustic) and ultrasound (US) imaging. Pulsed near-infrared laser light of various wavelengths is emitted and the associated acoustic feedback (photoacoustic effect) provides complementary information regarding tissue composition/functionality based on the presence of endogenous chromophores, such as haemoglobin; this photoacoustic data can be overlaid on the associated US image.	**Class B**
130	Orthopaedic x-ray ruler	A device used in an orthopaedic clinical setting to establish an accurate measurement of length or size related to a bone structure (i.e., length, thickness, or other aspects) when this is being viewed by the surgeon during fluoroscopy. It includes a series of notches and holes that clearly show up on the x-ray image demonstrating the distances of the viewed bone.	**Class A**
131	Panoramic digital X-ray sensor	A sensor used in combination with a diagnostic digital dental X-ray imaging device that is specifically designed for panoramic imaging of teeth, jaw, and oral structures. The sensor consists of a CCD and other components, and comprises a sensor drive circuit and a signal processing circuit.	**Class B**
132	Panoramic/tomographic dental x-ray system (orthopantomography system) application software	An application or operating data program designed for use in, or together with a panoramic/tomographic dental x-ray system configuration.	**Class C**

S. No.	Device name	Intended use	Risk Classification
133	Paranasal ultrasound probe	A reusable or single-use ultrasound transducer assembly enclosed in a fluid-resistant, acoustically and electrically insulated housing that is intended to be inserted into and positioned in the paranasal sinuses by the operator. The device is also called an endoscopic ultrasound probe or ultrasound endoscopic transducer to be used in the paranasal sinuses. the device is typically incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device or a needle biopsy device. The device is composed of either a single transducer element or an array of transducer elements (also called piezoelectric elements, active elements, or crystals), damping, backing, and matching materials.	**Class B**
134	PET infusion system	An assembly of devices intended to deliver accurate doses of 18F Fluorodeoxyglucose (FDG) radiopharmaceuticals and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. It may also be used to provide effective radiation shielding to medical personnel from Fluorine-18 (18F) radiation exposure during nuclear medicine diagnostic procedures. (Not meant for pediatric populations).	**Class C**
135	PET system	An assembly of devices comprising a diagnostic, positron emission tomography (PET) imaging system used to detect, record, quantify and analyse 511 kilo-electronvolt (keV) photon emission patterns resulting from annihilation reactions produced during the decay of positron emitting radiopharmaceuticals. It produces three-dimensional (3-D) tomographic digital cross-sectional physiological images representing distribution patterns of positron emitting radiopharmaceuticals ingested by, or injected into the patient.	**Class C**
136	PET system application software	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a positron emission tomography (PET) imaging system configuration. A basic set of applications programs and routines is included with such computer-controlled imaging systems and they can be upgraded to correct	**Class B**

S. No.	Device name	Intended use	Risk Classification
		programming errors or to add new system capabilities.	
137	PET/CT system	A diagnostic radiological imaging system that is a combination of a positron emission tomography (PET) camera system for nuclear medicine (NM) images, and a computed tomography (CT) camera system for x-ray images. The nuclear medicine images and the x-ray images may be registered and displayed in a fused format (overlaid in the same orientation) for the anatomical localization of the nuclear medicine data (i.e., distribution of radiopharmaceuticals). The PET and CT portions of the system may be used independently or in combination.	**Class C**
138	PET/MRI system	A diagnostic radiological imaging system that is a combination of a positron emission tomography (PET) camera system for nuclear medicine (NM) images, and a magnetic resonance imaging (MRI) system for magnetic resonance images. The nuclear medicine images and the magnetic resonance images may be registered and displayed in a fused format (overlaid in the same orientation) for the anatomical localization of the nuclear medicine data (i.e., distribution of radiopharmaceuticals). The PET and MRI portions of the system may be used independently or in combination.	**Class C**
139	Photofluorographic x-ray system	A photofluorographic x-ray system is a device that includes afluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body.	**Class C**
140	Pneumoencephalographic chair, non powered	A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).	**Class B**
141	Positron CT combined SPECT system	A system capable of performing both SPECT examination and positron CT (PET) examination	**Class C**

S. No.	Device name	Intended use	Risk Classification
142	Radiographic film cassette/X-ray cassette	A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film	**Class B**
143	Radiographic film/cassette changer	A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.	**Class B**
144	Radiographic film/cassette changer programmer	A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.	**Class B**
145	Radiologic quality assurance instrument	A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.	**Class A**
146	Radiological computer aided triage and notification software	Radiological computer aided triage and notification software is an image processing software intended to aid in prioritization and triage of radiological medical images. The device notifies a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis of those images performed by the device.	**Class C**
147	Radiological computer-assisted diagnostic software for lesions suspicious of cancer	A radiological computer-assisted diagnostic software for lesions suspicious of cancer is an image processing prescription device intended to aid in the characterization of lesions as suspicious for cancer identified on acquired medical images such as magnetic resonance, mammography, radiography, or computed tomography. The device characterizes lesions based on features or information extracted from the images and provides information about the lesion(s) to the user.	**Class C**
148	Radionuclide dose calibrator	A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.	**Class B**
149	Radionuclide rebreathing system	A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere).	**Class C**

S. No.	Device name	Intended use	Risk Classification
150	Rectal/vaginal ultrasound imaging transducer	An invasive component of an ultrasound imaging assembly designed to be positioned within the vagina and/or rectum, either manually or under endoscopic guidance, for ultrasound imaging from within the vagina/rectum. It may be intended for wired or wireless data transfer and may be intended for use with a dedicated ultrasound system or with an off-the-shelf device (e.g., smartphone) with dedicated software installed. This is a reusable device.	**Class B**
151	Software for electrocardiograph with ultrasonic diagnostic system	A software, which is designed to process data obtained from an electrocardiograph with ultrasound diagnostic system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	**Class C**
152	SPECT system application software	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a positron emission tomography (PET) imaging system configuration. A basic set of applications programs and routines is included with such computer-controlled imaging systems and they can be upgraded to correct programming errors or to add new system capabilities.	**Class B**
153	SPECT system, annular detector array	An assembly of devices comprising a diagnostic, stationary, single photon emission computed tomography (SPECT) system designed exclusively for use in tomographic imaging applications. It detects, records, quantifies and analyses radionuclide emissions produced during the decay of radiopharmaceuticals or other radiation emitting materials injected into, or ingested by, a patient. Its imaging capabilities include static and dynamic imaging applications and three-dimensional (3-D) digital image reconstruction/display at any angle including axial, coronal and sagittal planes.	**Class C**
154	SPECT system, rotating detector head	An assembly of devices comprising a diagnostic single photon emission computed tomography (SPECT) system that is a three-dimensional (3-D) tomographic imaging gamma camera-based system used to detect, record, quantify and analyse radionuclide emissions (primarily gamma rays) produced during the decay of radiopharmaceuticals or other radiation	**Class C**

S. No.	Device name	Intended use	Risk Classification
		emitting materials injected into, or ingested by, a patient.	
155	SPECT/CT system	An assembly of diagnostic devices that comprise a radiological imaging system that is a combination of a single photon emission computed tomography (SPECT) camera system for nuclear medicine (NM) images, and a computed tomography (CT) camera system for x-ray images. The nuclear medicine images and the x-ray images may be registered and displayed in a fused format (overlaid in the same orientation) for the anatomical localization of the nuclear medicine data (i.e., distribution of radiopharmaceuticals). The SPECT and CT portions of the system may be used independently or in combination and the images may be transferred to other systems for radiation therapy planning or additional processing.	**Class C**
156	Spot-film device	A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.	**Class B**
157	Surgical ultrasound imaging transducer	A hand-held ultrasound imaging transducer assembly designed to be positioned within a surgical site for localized intraoperative imaging applications. This group of devices includes ultrasound imaging transducer assemblies used with A-mode, B-mode, M-mode, Doppler, colour Doppler (CD), and duplex (combination imaging, Doppler and/or colour flow) scanning capabilities. This is a reusable device.	**Class C**
158	Thyroid-uptake nuclear medicine system	An assembly of diagnostic devices that comprise a non-imaging nuclear medicine system designed primarily for radioactive iodine related thyroid uptake measurement and analysis applications. It typically includes a multichannel analyser, computer, scintillation detector, detector support equipment, an operator's console, video	**Class B**

S. No.	Device name	Intended use	Risk Classification
		display, well counter detector, collimator, shielding, and application software.	
159	Tissue specimen x-ray tomography system	An assembly of devices designed to produce an x-ray image of a tissue sample (e.g., stereotactic biopsy cores taken during mammographic procedures) and/or an amputated body part, by generating and controlling x-ray beams and recording the absorption patterns of the x-rays.	**Class A**
160	Transilluminator for breast evaluation/Breast transilluminator (Diaphanoscope)	A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700-1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.	**Class C**
161	Transoesophageal vascular ultrasound monitor	A mains electricity (AC-powered) device intended to be used for monitoring cardiac output and/or fluid status through connection to a dedicated probe, which is placed in the oesophagus to measure blood flow in the descending aorta. It is based on measuring the ultrasonic frequency shift between transmitted and reflected signals (Doppler principle) and is displayed on the monitor as a velocity/time waveform. It is typically used during a surgical procedure or in intensive care.	**Class B**
162	Transoesophageal vascular ultrasound probe	A device intended to be inserted into the oesophagus, orally or nasally, to continuously measure blood flow in the descending aorta by ultrasonic Doppler technology for assessment of cardiac output and/or fluid status. It has multiple sensors at the distal end and a connector at the proximal end. It is typically used during general anaesthesia or in intensive care. This is a single-use device.	**Class B**
163	Ultrasonic amplifier	A unit used to amplify signals transmitted from the probe of an ultrasound imaging system. This is used with an ultrasound system in the event the quality of original data transfer is lowered by the distance	**Class B**

S. No.	Device name	Intended use	Risk Classification
		between the console and the imaging probe in the ultrasound system.	
164	Ultrasonic pulsed doppler imaging system	An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion.	**Class B**
165	Ultrasonic pulsed echo imaging system	An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver.	**Class B**
166	Ultrasound aspiration biopsy procedure kit	A collection of sterile devices that includes a biopsy needle and other supplies used to perform an ultrasound-guided aspiration sampling of tissue. The needle tip must provide a clearly visible image during ultrasound imaging. This is a single-use device.	**Class B**
167	Ultrasound contrast medium, transuterine administration	A substance/formulation (e.g., solution, gel, foam) intended to be administered into the female reproductive tract, via the vagina/uterus, to enhance diagnostic ultrasound images, typically for the evaluation of the uterine cavity and/or fallopian tube patency. (Invasive devices for application not included)	**Class A**
168	Ultrasound endoscope balloon, Hevea-latex	A sterile balloon-like cap made of Hevea natural rubber latex (NRL) designed to be placed on the distal end of an ultrasound endoscope and inflated to make contact with the wall of the viscus to enable a higher-quality ultrasound image during echo-endoscopy, typically of the gastrointestinal or respiratory tract. It is inflated with water through the endoscope.	**Class B**

S. No.	Device name	Intended use	Risk Classification
169	Ultrasound endoscope balloon, synthetic polymer	A sterile balloon-like cap made of a synthetic-polymer (e.g., silicone) designed to be placed on the distal end of an ultrasound endoscope and inflated to make contact with the wall of the viscus to enable a higher-quality ultrasound image during echo-endoscopy, typically of the gastrointestinal or respiratory tract. It is inflated with water through the endoscope.	**Class B**
170	Ultrasound imaging system application software	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a diagnostic ultrasound system configuration. A basic set of applications programs and routines are included with such computer-controlled imaging systems and they can be upgraded to correct programming errors or to add new system capabilities.	**Class B**
171	Ultrasound imaging system multi-transducer connection unit	An electronic device intended to be used with an ultrasound (US) imaging system to enable the simultaneous connection of multiple hand-held US transducers so the user can conveniently switch between transducers as required. It is a unit with multiple transducer ports and is typically attached to the US imaging system stand.	**Class B**
172	Ultrasound imaging system operation software	Mainframe or personal computer (PC) based operating system software (or firmware) specific to the central processing unit (CPU) incorporated into a diagnostic ultrasound system configuration. This includes the software or firmware based programs and routines supplied by the computer manufacturer that drive a specific computer in the performance of its tasks and assists the operators, applications programmers and programs with various supporting functions.	**Class B**
173	Ultrasound imaging system operator console	A device that is a component of a diagnostic ultrasound imaging system that functions as the primary control panel. It includes hardware and software that allows for image display, processing, analysis, archiving and retrieval. It typically includes the capabilities to be interfaced into a picture archiving and communication system (PACS), a local area network (LAN), a radiology information system (RIS) or a hospital information system (HIS). It contains the primary controls for the direct operation of the ultrasound system and is typically incorporated in the system design	**Class B**

S. No.	Device name	Intended use	Risk Classification
		as is the case with mobile or portable ultrasound systems.	
174	Ultrasound imaging system tracking positioner, reusable (ultrasound transducer bracket)	A metal or plastic bracket intended to be applied to a hand-held ultrasound (US) transducer for the repeatable positioning (detach from/reattach to same place) of an electromagnetic (EM) sensor and/or needle guide on the transducer. It may be used in conjunction with an EM device tracking system and is intended for applications involving needle guidance and tracking such as ablation, core tissue biopsy, fluid aspiration, therapeutic delivery and vascular access. (transducer and sensor are not included)	**Class B**
175	Ultrasound imaging transducer positioning unit	A unit used to position an ultrasound system imaging transducer that is inserted into the body through an endoscope. This device is an accessory to a diagnostic ultrasound imaging system and it transmits electrical signals that, after processing, will display the position of a the transducer on a monitor. This unit will assist the endoscopist in the placement of the working transducer (the probe) and to allow monitoring of the movement after placement.	**Class B**
176	Ultrasound imaging transducer washer-disinfector (chemical)	A dedicated electrically-powered unit intended to be used to wash and disinfect ultrasound imaging transducers with the use of appropriate cleaning methods and chemical disinfection. It is typically a stand-alone unit with a washing/disinfecting chamber designed to accept an ultrasound imaging transducer (probe). Not intended for end disinfection.	**Class B**

S. No.	Device name	Intended use	Risk Classification
177	Ultrasound system synchronizer	A physiological monitoring device used as one component in a diagnostic ultrasound system. This device produces signals which can synchronize imaging acquisition and data collection with specific measurable, physiological parameters, such as the starting point of a patient's respiratory or cardiac cycle. It is used mainly to reduce artifacts and to increase the signal-to-noise ratio in real-time ultrasonic imaging and in video imaging.	**Class B**
178	Ultrasound-guided laser thermal therapy needle guide positioning system	An assembly of noninvasive devices intended for use during soft-tissue lesion treatment by ultrasound-guided laser thermal therapy, to provide software-based simulation of tissue thermal damage for assisting the manual positioning of percutaneous needles through which laser applicators (not included) are introduced. It consists of an electrically-powered interface/display and needle guides for attachment to a body-surface ultrasound (US) imaging probe/transducer; the system overlays real-time US images [from a separate US system] with the predicted laser thermal effect	**Class C**
179	Vascular ultrasound system control unit	A mains electricity (AC-powered) external device, which may include internal rechargeable batteries, intended to be used to indicate (visually and/or sonically) blood flow in a peripheral blood vessel, through connection to a dedicated probe/catheter (not included), using ultrasound/Doppler/transit time technology. It may be intended to locate and assess the extent of vascular flow restriction (e.g., clots, stenosis, mechanical damage) or to monitor blood flow in association with microvascular surgery.	**Class B**
180	X-ray film cassette, automatic film changing	A housing for x-ray film specifically designed to be used in, and work as part of, an automated x-ray film changing system. The housing is intended to be loaded with x-ray film under appropriate darkroom conditions, and is then inserted into the loading magazine of the film changing system. After exposure, it is held in a receiving magazine until the operator removes it for final processing.	**Class B**
181	X-ray film cassette, manual	A device used in medical imaging applications to shield x-ray film from exposure to room light during transport and insertion into a diagnostic imaging system, film formatter, or film processor.	**Class B**

S. No.	Device name	Intended use	Risk Classification
182	X-ray film ruler	A device used in radiology to superimpose accurate measurements of length (i.e., inches or millimetres) onto an x-ray film so that these measurements remain as a permanent feature of that x-ray against the anatomical structure that has been captured. It is made of x-ray translucent material (e.g., plastic) whilst the graduations are not translucent and therefore show on the exposed x-ray film.	**Class A**
183	X-ray image intensifier	A device that converts an x-ray image into a light image, then to an electronic image and finally back to a light-based image of diminished size and increased brightness. It is primarily used in fluoroscopic, angiographic, cine-fluorographic x-ray, and digital x-ray applications as it outputs an image small enough to be coupled to cine, television or spot-film cameras.	**Class B**
184	X-ray system computer, diagnostic, general-purpose	A dedicated mainframe computer, personal computer (PC) or PC based platform and associated hardware, firmware, and operating system software used specifically to control and monitor the operation of a general-purpose medical x-ray system and associated image processing, display and analysis functions.	**Class C**
185	X-ray system synchronizer	A physiological monitoring unit used as a component of a diagnostic x-ray system, e.g., fluoroscopy, angiography or general-purpose, that produces a signal which enables image formation or data collection to be synchronized with a specific measurable physiological parameter, e.g., the beginning of a patient's respiratory or cardiac cycle. It is primarily used for the purpose of artifact reduction or enhancement of signal-to-noise ratios in various real-time or dynamic diagnostic x-ray applications. It is sometimes referred to as a gated imaging accessory or trigger.	**Class C**
186	X-ray/CT combined cardiovascular diagnostic X-ray system	A system combining a diagnostic X-ray computed tomography (CT) and a diagnostic cardiovascular fluoroscopy system.	**Class C**

Name of Category:

Radiotherapy

Total No. of Devices:

114

Category: Radiotherapy

S.No.	Device name	Intended use	Risk Class
1	Absorbable perirectal spacer	An absorbable perirectal spacer is composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum.	**Class C**
2	Absorbable tissue spacer for radiotherapy	An absorbable material used to reduce radiation exposure of normal tissue during radiotherapy by implanting surgically or percutaneously between tissue, internal organs, etc., to make a space between the malignant tumor and normal tissue.	**Class D**
3	Applicator for bile duct manual brachytherapy	A manual brachytherapy applicator specifically designed for bile duct radiation therapy. An applicator designed to have a configuration that facilitates manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bile duct.	**Class C**
4	Applicator for bile duct remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bile duct radiation therapy. It is designed to be temporarily implanted in the bile duct. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	**Class C**
5	Applicator for bladder manual brachytherapy	A manual brachytherapy applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bladder.	**Class C**

S.No.	Device name	Intended use	Risk Class
6	Applicator for bladder remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bladder radiation therapy. It is designed to be temporarily implanted in the bladder. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	**Class C**
7	Applicator for brachytherapy non-central circulatory general-purpose manual	A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy, and placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the non-central circulatory system.	**Class C**
8	Applicator for brachytherapy non-central circulatory general-purpose remote after loading	A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the non-central circulatory system.	**Class C**
9	Applicator for bronchial manual brachytherapy applicator	A manual brachytherapy applicator specifically designed for temporarily use in bronchial radiation therapy. A single or module applicator designed to facilitate manual placement (placement using an endoscope or positioning, placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources.	**Class C**

S.No.	Device name	Intended use	Risk Class
10	Applicator for bronchial remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bronchial radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the bronchus. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	**Class C**
11	Applicator for cervical/endometrial manual brachytherapy	A manual brachytherapy applicator specifically designed for uterine cervix or intrauterine radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, placement with an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites.	**Class C**
12	Applicator for Cervical/endometrial remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically designed for uterine, cervical, or intrauterine radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the uterus, cervix and endometrium.	**Class C**
13	Applicator for esophagus manual brachytherapy	A manual brachytherapy applicator specifically designed for esophagus radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the esophagus. It may be designed to be standard in configuration or to handle specific radiation sources.	**Class C**

S.No.	Device name	Intended use	Risk Class
14	Applicator for esophagus remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for esophagus radiation therapy. It is designed to be temporarily implanted in the esophagus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	**Class C**
15	Applicator for eye manual brachytherapy	A template with a groove on the one side. The groove shows the position of the brachytherapy source that is manually, temporarily delivered to the eye surface. The other side is shielded.	**Class C**
16	Applicator for eye remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for eye radiation therapy. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	**Class C**
17	Applicator for nasopharynx manual brachytherapy	A manual brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the nasopharynx.	**Class C**

S.No.	Device name	Intended use	Risk Class
18	Applicator for nasopharynx remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the nasopharynx.	**Class C**
19	Applicator for neck manual brachytherapy	A manual brachytherapy applicator specifically designed for neck radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the neck tissues.	**Class C**
20	Applicator for neck remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for neck radiation therapy. It is designed to be temporarily implanted in the neck tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	**Class C**
21	Applicator for pancreas manual brachytherapy	A manual brachytherapy applicator specifically designed for pancreatic radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement, or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the pancreas. It may be designed to be standard in configuration or to handle specific radiation sources.	**Class C**

S.No.	Device name	Intended use	Risk Class
22	Applicator for pancreas remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for pancreatic radiation therapy. It is designed to be temporarily implanted in the pancreas. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	**Class C**
23	Applicator for prostate manual brachytherapy	A manual brachytherapy applicator specifically designed for prostate radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement or removal with a trigger loading device, an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the prostate gland. It may be designed to be standard in configuration or to handle specific radiation sources.	**Class C**
24	Applicator for prostate remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for prostate radiation therapy. It is designed to be temporarily implanted in the prostate gland. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	**Class C**
25	Applicator for rectal/anal manual brachytherapy	A manual brachytherapy applicator specifically designed for rectal and/or anal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the rectum and/or anus.	**Class C**

S.No.	Device name	Intended use	Risk Class
26	Applicator for rectal/anal remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for rectal or anal radiation therapy. It is designed to be temporarily implanted in the rectum or anus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	**Class C**
27	Applicator for tongue manual brachytherapy	A manual brachytherapy applicator specifically designed for lingual radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the tongue and the surrounding tissues. It may be designed to be standard in configuration or to handle specific radiation sources.	**Class C**
28	Applicator for tongue remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for tongue or oral cavity radiation therapy. It is designed to be temporarily implanted in the tongue or the surrounding tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	**Class C**
29	Applicator for vaginal manual brachytherapy	A manual brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites.	**Class C**

S.No.	Device name	Intended use	Risk Class
30	Applicator for vaginal remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the vagina.	**Class C**
31	Blood vessel manual brachytherapy applicator	A manual brachytherapy applicator designed exclusively for blood vessel radiotherapy. Most commonly, it is used to prevent formation of plaque, stenosis and restenosis in blood vessels after surgery. A single or module device designed to facilitate manual placement (placement and removal under endoscopy or using an image diagnostic system) of single or multiple therapeutic radiation sources in the treatment site.	**Class D**
32	Blood vessel remote after loading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for radiotherapy in blood vessels. This treatment is used to prevent plaque formation. and stenosis in blood vessels after surgery. It is designed for temporary implantation in a blood vessel, and serves as a guide for computer-controlled temporary placement and removal of single or multiple therapeutic radiation sources at treatment sites.	**Class D**
33	Brachytherapy needle	A sterile, sharp bevel-edged, hollow tubular metal instrument that is used to inject radionuclide into a body cavity or tissue as a source of nuclear radiation for cancer therapy (brachytherapy).	**Class B**
34	Brachytherapy radionuclide phantom, anthropomorphic	A device that consists of preserved human or animal tissue, or a two or three-dimensional (3-D) tissue-equivalent model designed to simulate the functional, physical, or a combination of these characteristics of normal or diseased human organs.	**Class B**

S.No.	Device name	Intended use	Risk Class
35	Brachytherapy system chair	A mains electricity (AC-powered) device (a chair or stool) that is a component of a brachytherapy system and which is specifically designed to support and position a patient during brachytherapy radiation treatments given by either a manual applicator or a remote after loading brachytherapy system applicator.	**Class B**
36	Brachytherapy system remote after loading source safe	A component of a remote after loading brachytherapy system consisting of a shielded vault, and associated source retraction and extrusion mechanisms, alarms, and related mechanical, electronic and software controls, used to shield the brachytherapy sources in order to protect system operators, brachytherapy patients and others from the continuous emissions of the radioactive brachytherapy source(s) when they are not in use.	**Class C**
37	Brachytherapy system remote after loading source transfer tube	The transfer tube, when attached to the applicator and the after loading system, provides a continuous closed passage that allows for moving either a radioactive source(s) and/or positioning markers from the shielded source storage compartment of the remote after loading brachytherapy system into appropriate positions within a brachytherapy applicator that has been positioned at a location either on the surface of, or within, the patient.	**Class C**
38	Brain manual brachytherapy applicator	An applicator specifically designed for brain radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, placement under endoscopy, or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in the brain.	**Class D**

S.No.	Device name	Intended use	Risk Class
39	Brain remote after loading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for brain radiotherapy for temporary implantation in the body. It serves as a computer- controlled guide for temporary placement and removal of a single or multiple therapeutic radiation sources in the brain.	**Class D**
40	Breast brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast.	**Class C**
41	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast. It is typically designed for temporary implantation within the breast and serves as a guide for computer-controlled placement and removal of single or multiple radioactive sources.	**Class C**
42	Breast ductography cannula	A thin, sterile, semi-rigid or rigid metal tube that is inserted into the nipple of the female breast to inject a contrast medium into the lactiferous ducts to enhance their visualization during a radiographic procedure.	**Class C**
43	Central circulatory general-purpose manual brachytherapy applicator	A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the central circulatory system.	**Class D**
44	Central circulatory general-purpose remote after loading brachytherapy applicator	Intended to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the central circulatory system.	**Class D**

S.No.	Device name	Intended use	Risk Class
45	Central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device does not equip a remotely controlled radiation source transporter.	**Class D**
46	Central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system to be placed permanently in the body for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source, which is permanently placed manually, is designed to achieve compatibility with tissues. The radiation source can be selected from the following forms – e.g., microsphere, globe, stent, seed, and wire- in order to generate low-energy photons, beta particles, or alpha particles.	**Class D**
47	Central circulatory remote after loading brachytherapy therapeutic radionuclide source	A device for the central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor.	**Class D**
48	Central circulatory remote after loading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	**Class D**

S.No.	Device name	Intended use	Risk Class
49	Central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system that uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor, and is placed in the body temporarily, and removed after the pre-determined treatment period. The radiation source, which is temporarily inserted manually, is supplied in various forms – e.g., encapsulated, sealed, plated, foiled, or embedded.	**Class D**
50	Compact thermoluminescent dosimetry electrometer	Thermoluminescence dosimeter (TLD) is used to measure the radiation dose emitted to the phantom, eyes and other organs with high radio sensitivity.	**Class A**
51	Conformal Brachytherapy Source	The intended use of the device is for the treatment of cancer by temporary intraoperative or surface irradiation. The device contains radioactive material with activity up to 200 mci and is indicated for treatment of temporary intraoperative, interstitial, intracavitary or surface application to treat selected localized tumors.	**Class C**
52	Coronary artery brachytherapy system applicator, manual	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a manual afterloading brachytherapy system	**Class D**
53	Coronary artery brachytherapy system applicator, remote afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a remote-controlled afterloading brachytherapy system	**Class D**

S.No.	Device name	Intended use	Risk Class
54	Fluoroscopy/angiography table, powered	A powered table designed to support and position a patient during fluoroscopy/angiography typically in conjunction with a cardiovascular intervention or other minimally-invasive surgical intervention (e.g., biopsy). It has a flat table top with electronic controls for table top positioning and/or motion relative to the x-ray beam. It is not dedicated to breast biopsy, and is not intended for other specialized surgeries (i.e., it is not a specialized operating table with x-ray transparent features).	**Class B**
55	Gamma knife for radiotherapy/surgery	A set of devices that are designed to uses very precise beams of gamma rays to treat an area of disease (lesion) or growth (tumor), especially in the brain, upper spine and in certain cases, vascular abnormalities.	**Class D**
56	General-purpose brachytherapy system applicator, manual	A general-purpose brachytherapy applicator designed to facilitate delivery of radiation therapy treatments that are not specific to a particular anatomical region. It is an individual or modular device designed to facilitate manual placement, e.g., puncture, topical placement, endoscopically guided placement or diagnostic imaging system guided placement, and removal of single or multiple radioactive sources at a treatment site.	**Class C**
57	General-purpose brachytherapy system applicator, remote-afterloading	A general-purpose remote-afterloading brachytherapy applicator intended to be used to facilitate the delivery of radiation therapy treatments in a range of anatomical regions (e.g., liver, kidneys, lungs, gastrointestinal tract). It is designed for temporary introduction into the body and functions as a guide for computer-controlled placement and removal of single or multiple radioactive sources in a treatment area.	**Class C**

S.No.	Device name	Intended use	Risk Class
58	High-frequency hyperthermia system	A system used to generate high-temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases.	**Class C**
59	Interventional radiology percutaneous-access kit	A collection of various instruments/devices (e.g., introducer sheath, dilator, guides, cannula, needle, angiographic catheter) intended to be used for percutaneous body-access to facilitate a radiological image-guided interventional radiology or surgical procedure [e.g., bile duct biopsy, percutaneous transhepatic cholangiogram, non-vascular drainage procedures, ultrasound-guided spinal surgery]. Some types are designed to function as a channel to facilitate the introduction of radiological image guidance devices (e.g., ultrasound probe/transducer) [not included]. It does not contain pharmaceuticals.	**Class C**
60	Intra-vaginal organ positioning device for diagnostic imaging and radiotherapy	A device that is specifically designed to be inserted in the vagina to properly position and fix the surrounding organs such as uterine cervix, rectum, and urinary bladder for image diagnosis or radiotherapy. This device is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	**Class B**
61	Laser irradiation therapy kit	A kit includes a puncture needle, a guide wire, and a guiding sheath for guiding probes (used for laser irradiation therapy, for example). Not all of the components are included; in some products, two or more of components are integrated into one.	**Class B**
62	Living tissue radiotherapy system	A low energy X-ray therapy system designed to treat adjacent tumor lesions with high dose X-rays by placing soft X-ray beams from 5 to 50 kV inside the tumor tissue. It is used in both intraoperative radiation and stereotactic localized radiation therapy.	**Class C**

S.No.	Device name	Intended use	Risk Class
63	Manual brachytherapy source, permanent implant	A device that is a naturally-occurring, accelerator- or reactor-produced radioactive isotope and intended to be permanently implanted into the body in order to deliver curative or palliative radiotherapy treatments. Manually implanted sources intended for permanent implantation are designed to be histocompatible. It may take the form of, e.g., microspheres, spheres, stents, seeds or wires selected for producing low energy photons, beta or alpha particles.	**Class D**
64	Manual brachytherapy source, temporary placement	A device that is a naturally-occurring, accelerator- or reactor-produced radioactive isotope in a form that is intended for temporary placement in the body and removal after a specified treatment time. It is used in brachytherapy applications that require direct manual or endoscopically-guided placement and removal. Manually inserted sources intended for temporary placement come in a variety of forms, e.g., encapsulated, sealed, plated, foil or embedded sources.	**Class C**
65	Manual brachytherapy system	An assembly of therapeutic, independent devices, manually brought together and intended to deliver a palliative or therapeutic radiation dose to an anatomical region from radionuclide sources. Medical personnel manually place multiple radioactive sources in appliances and applicators for either permanent or temporary delivery at the topical, interstitial, intraluminal, or intracavitary brachytherapy treatment site.	**Class C**
66	Manual-afterloading brachytherapy system source delivery procedure kit	A collection of sterile devices intended to dispense/collect hydraulic fluid used to deliver the radiation source train of a manual-afterloading brachytherapy system source transfer device to/from the delivery catheter/applicator. It consists of disposable devices such as syringes, fluid collection bags, adaptors/connectors.	**Class B**

S.No.	Device name	Intended use	Risk Class
67	Manual-afterloading brachytherapy system storage container	A non-sterile radiation-shielding plastic box intended to store a manual-afterloading brachytherapy system. It is typically temporarily used as a safety container to prevent radiation leakage in the event of procedural difficulties.	**Class C**
68	Medical charged- particle radiation therapy system	A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy.	**Class C**
69	Medical neutron radiation therapy system	A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy	**Class C**
70	MOSFET radiation therapy dosimetry system	An assembly of devices using metal oxide semiconductor field-effect transistor (MOSFET) technology intended to be used for on-the-spot patient or anthropomorphic radiation dose verification and monitoring during radiation therapy and radiology procedures. Applications typically include radiation oncology therapy and dosimetry, treatment plan verification for in vivo dosimetry, brachytherapy, intraoperative radiation therapy, image-guided radiation therapy, and research.	**Class B**
71	Non-central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy.	**Class C**
72	Non-central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device which is histocompactible and containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be permanently implanted in the body for radiation therapy requiring treatment or symptomatic treatment.	**Class C**

S.No.	Device name	Intended use	Risk Class
73	Non-central circulatory remote after loading brachytherapy therapeutic radionuclide source	A device for the non-central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor.	**Class C**
74	Non-central circulatory remote after loading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	**Class C**
75	Non-central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be temporarily implanted in the body and to be removed after a prescribed duration of treatment. Used in brachytherapy, the device is placed and removed manually or under endoscopic observation.	**Class C**
76	Patient positioning device for breast diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a female patient's breasts and chest for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
77	Patient positioning device for extremity diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a patient's arms and legs for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
78	Patient positioning device for pelvis diagnostic imaging and radiotherapy	The device that consists of frames, plates, or other parts, and is specifically designed to properly position and fix the patient's abdomen and pelvic region for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**

S.No.	Device name	Intended use	Risk Class
79	Patient positioning device for whole body diagnostic imaging and radiotherapy	A device that consists of fixed or adjustable parts (e.g., frames and plates), and is specifically designed to properly position and fix the patient's whole body for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
80	Patient Positioning System, Ultrasound	An assembly of devices used to locate, with ultrasound, internal soft-tissue anatomy that moves relative to external or bony landmarks, to enable subsequent adjustment of the patient for precise external beam radiation treatment of the target tissue. It typically includes an ultrasound imaging system, computerized workstation(s), optical tracking devices, and dedicated software.	**Class C**
81	Post Breast Biopsy Hemostatic Breast Compression Device	Intended to achieve and maintain hemostasis of a breast biopsy wound site.	**Class C**
82	Powered neutron therapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from the nuclear reactor, etc.	**Class B**
83	Powered patient table for accelerator	A bed operates by programmable for electric radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses medical linear accelerator or non-linear accelerator.	**Class B**
84	Powered radiation therapy patient support assembly	A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy	**Class C**

S.No.	Device name	Intended use	Risk Class
85	Powered radionuclide brachytherapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically.	**Class B**
86	Powered remote irradiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote cobalt 60 radiotherapy apparatus and other remote radionuclide radiotherapy apparatuses.	**Class B**
87	Powered X-rays radiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus.	**Class B**
88	Radiation therapy beam-shaping block	A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source	**Class C**
89	Radiation therapy digital imager	An automated device that is typically mounted on the gantry of a linear accelerator and intended to produce digital images of x-rayed anatomical landmarks to guide radiation treatment (e.g., tracking/targeting tumours). The device may be a digital imaging panel (e.g., of silicon) on robotic arms; it may also have an x-ray source to generate higher quality images.	**Class C**
90	Radiation therapy simulation system	A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced.	**Class C**

S.No.	Device name	Intended use	Risk Class
91	Radiological image marker, implantable	A device intended to be implanted within the body, either temporarily or permanently, to create identifying marks that can be seen on radiographic film or digital images. It is typically in the form of a wire, needle, bead, clip, stent-like tube, washer or fluid, and used to locate and delineate a tumour, lesion, or other site of interest. It is made from materials compatible with the imaging system with which it is intended to be used [e.g., magnetic resonance imaging (MRI), x-ray, or nuclear medicine]; it may be intended for use during radiotherapy procedures.	**Class C**
92	Radionuclide brachytherapy source	A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy	**Class C**
93	Radionuclide dynamic function testing equipment	A device used to measure and record temporal variations of radioisotope concentrations in the body. Specialized devices, such as devices for thyroid uptake measurement, renograms, and radioisotope blood volume measurement, are included.	**Class B**
94	Radionuclide radiation therapy system	A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body.	**Class C**
95	Radionuclide source for remote irradiation therapy	Radiation sources generated in a reactor and used as in a remote after loading system designed to deliver a therapeutic radiation beam to a target anatomical area. The radiation sources incorporated as a component of the remote after loading system are generally sealed.	**Class C**

S.No.	Device name	Intended use	Risk Class
96	Radionuclide system contour detector for remote irradiation therapy	Intended to precisely determine the outline of the area of the body to be irradiated. Usually, the information obtained from this device is entered into a radiotherapy planning system and utilized for the radiotherapy plan.	**Class C**
97	Real-time position management respiratory gating system, optical	An assembly of electronic devices designed to track the respiratory pattern of a patient by means of optical technology to correlate tumour position with the respiratory cycle during radiation treatment planning, radiotherapy, computed tomography (CT) imaging, or other radiation procedures.	**Class C**
98	Rectal balloon for prostate immobilization	A rectal balloon for prostate immobilization is a single use, inflatable, non-powered positioning device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy.	**Class C**
99	Remote controlled radionuclide applicator system	A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy.	**Class C**
100	Remote-afterloading brachytherapy source	A device that is a naturally-occurring, accelerator or reactor produced-radioactive isotope used as a source of radiation in high or low dose rate remote afterloading brachytherapy systems designed to deliver curative or palliative radiotherapy treatments. Sources used in remote afterloading radiotherapy systems may come in a variety of strengths and physical forms, e.g., single encapsulated source (sealed source), ribbons, plated, foil or embedded sources or contained radioactive liquids or gels.	**Class C**

S.No.	Device name	Intended use	Risk Class
101	Remote-afterloading brachytherapy system	An assembly of devices using a remotely-controlled radioactive source transport system designed to deliver a therapeutic or palliative radiation dose from a single source or source train to an anatomical region by placing the radioactive source(s) temporarily on or in the treatment site.	**Class C**
102	Stereotactic radiosurgical system	An assembly of devices designed to deliver a therapeutic radiation dose to an anatomical region from external beams produced from multiple radionuclide sources arranged in a fixed focal point collimated array; typically used to treat brain, neck, breast and spinal tumours. It typically consists of: 1) a stereotactic positioning device attached to the patient to define the three-dimensional (3-D) co-ordinates of the treatment site; 2) fixed diameter collimators; 3) high-density beam blockers; 4) a shielded housing to hold the sources, reducing room radiation; 5) a precision aligned array to cause the source beams to intersect at a single point; and 6) a moveable patient table.	**Class C**
103	Stereotactic radiotherapy accelerator system	A stereotactic radiation therapy system for treatment based on a linear accelerator (or microtron). The device may be used to inactivate lymphocytes.	**Class C**

S.No.	Device name	Intended use	Risk Class
104	Teletherapy radionuclide system table, powered	A device that is a component of a teletherapy radionuclide system (commonly known as a cobalt therapy machine) and that is a powered/programmable table specifically designed to position and support a patient during treatments administered using a therapeutic radionuclide teletherapy system (e.g., a Cobalt-60 teletherapy system). It has electronic and/or software controls for table top height and positioning. It can be a stationary or mobile unit, or incorporated as an integral component of a radionuclide teletherapy system or gantry configuration.	**Class B**
105	Teletherapy radionuclide system, conventional/Cobalt therapy machine	A stationary assembly of computer-based devices designed to deliver a therapeutic radiation dose to an anatomical region from a single external radiation beam produced by a radionuclide source, typically to treat malignant tumours; it does not provide image-guided radiation therapy (IGRT) functionality during treatment delivery.	**Class C**
106	Therapeutic x-ray high voltage generator	It is a device that is intended to supply and control the voltage and electrical energy to provide a therapeutic x-ray system (e.g., brachytherapy) with the power needed to produce an x-ray beam of the desired voltage (kV) and current (mA).	**Class B**
107	Ultraviolet Extracorporeal Photopheresis system	An assembly of devices used for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). It irradiates the leukocyte-rich fraction of peripheral blood by UVA radiation extracorporeally and returns back the treated and untreated blood to the patient. This system may or may not use a UV-active drug (either ingested by patient or injected into the leukocyte-rich fraction of the extracted peripheral blood).	**Class C**

S.No.	Device name	Intended use	Risk Class
108	Ultraviolet Photopheresis system blood set	A collection of devices used as part of a photopheresis system for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). It typically consists of tubing (patient and fluid lines), fluid/blood component bags, a dedicated centrifuge bowl, a photoactivation chamber, connectors, and clamps. It conducts blood from the patient to the system's main unit, aids in blood processing, and returns leukocyte-enriched and untreated components of the blood after irradiation. This is a sterile, single-use device.	**Class C**
109	Ultraviolet Photopheresis system lamp assembly	An assembly of ultraviolet A (UVA)-emitting tubular strip lights that is an exchangeable component of a photopheresis system, and used to irradiate blood components during extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL).	**Class C**
110	X-ray CT system for radiotherapy planning	A X-ray CT system that has a special configuration, containing hardware, software, etc. used in radiotherapy planning. It is used to determine the size and positioning of the therapeutic radiation field based on a series of treatment parameters to be generated.	**Class C**
111	X-ray radiation therapy system	An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy.	**Class C**
112	X-ray/CT combined linear accelerator system	A combined system of a linear accelerator system and an X-ray CT system for radiotherapy planning.	**Class C**
113	X-ray/CT combined particle radiotherapy equipment	A combined system of particle radiotherapy equipment and an X-ray CT system for radiotherapy planning.	**Class C**

S.No.	Device name	Intended use	Risk Class
114	X-ray/MR combined linear accelerator system	A system intended to provide treatment planning, image- guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment in indicated. The system operates on the principle of linear acceleration of electrons, providing a predictable radiation field in a beam of well-defined dimensions.	**Class C**

Name of Category:

Oncology

Total No. of Devices:

75

Category: Oncology

S. No.	Device name	Intended use	Risk Class
1	Accelerator system chair	A seat, typically with legs, that is a component of a therapeutic accelerator system, and used to support and position a seated patient during radiation therapy treatments involving the use of either a medical linear accelerator or non-linear accelerator.	**Class C**
2	Accelerator system quality assurance device	An instrument specifically designed to be used to check the calibration and performance of linear and non-linear medical accelerator systems used for radiation therapy applications, for quality assurance (QA) purposes.	**Class C**
3	Alternating electric field antimitotic cancer treatment system	An assembly of portable devices designed to apply low-intensity, intermediate-frequency (100-300 kHz) alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	**Class D**
4	Alternating electric field antimitotic cancer treatment system transducer array	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	**Class C**
5	Alternating electric field antimitotic cancer treatment system generator	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	**Class C**
6	Anorectal brachytherapy system applicator, remote-afterloading	A remote afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the rectum and/or anus.	**Class C**
7	Anorectal brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the rectum and/or anus.	**Class C**
8	Balloon kyphoplasty kit	A collection of sterile surgical instruments and devices used for the reduction of a vertebral compression fractures (VCFs) caused by trauma, cancer, or osteoporosis during a minimally invasive procedure commonly known as balloon kyphoplasty.	**Class C**
9	Bladder instillation buffer solution	A sterile buffer solution intended to be used exclusively for bladder instillation to help create an optimal environment necessary for the effective treatment of superficial bladder cancer with a chemotherapy agent.	**Class B**

S. No.	Device name	Intended use	Risk Class
10	Brachytherapy source spacer	A sterile, bioabsorbable device designed to separate radioactive sources of the seed type that are permanently implanted in close proximity to a selected localized tumour, to increase the distribution of radioactivity to the tumour.	**Class C**
11	Brachytherapy system remote-afterloading operator console	A mains electricity (AC-powered) component of a remote- afterloading brachytherapy system intended to function as the primary control panel for the remote afterloader. It typically includes hardware and software that allows for information display and/or transfer, data processing, analysis, and information archiving functions; it may also be intended to interface with other devices (e.g., radiation therapy treatment planning computer) as part of a picture archiving and communication system (PACS).	**Class C**
12	Breast 3-D infrared imaging/vascular analysis system	An assembly of mains electricity (AC-powered) devices intended for three-dimensional (3-D) breast imaging and breast vascular analysis, typically used with mammography screening to perform a breast cancer risk examination.	**Class C**
13	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast. It is typically designed for temporary implantation within the breast and serves as a guide for computer-controlled placement and removal of single or multiple radioactive sources. Included are various types of applicators such as hollow needles, tubes, or catheters, and their associated components. This is a single-use device.	**Class C**
14	Breast transilluminator	A mains electricity (AC-powered) transilluminating device with a built-in light source using low intensity emissions of visible light and near-infrared radiation (700 to 1050 nm) that is transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities. This device may also be known as a diaphanoscope.	**Class C**
15	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for intracorporeal (endosonography or endoscopic) ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast.	**Class C**
16	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for extracorporeal ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast	**Class B**

S. No.	Device name	Intended use	Risk Class
17	Cancer diagnostic probe	A device intended for detection of breast cance lesions of various subtypes intraoperatively by checking for tumour side margins.	**Class C**
18	Capsular tension ring	A circular band intended to be used to enhance the mechanical stability of a subluxated crystalline lens capsule in the presence of weak or absent supporting zonules.	**Class C**
19	Cervical cone knife	A surgical, manually-operated, instrument that is inserted into the vagina and designed for excising a sample of abnormal tissue, e.g., indicated by the presence of precancerous changes, from the cervix.	**Class C**
20	Cervical cytology scraper, single-use	A hand-held, manual, blunt surgical instrument designed to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a single-use device.	**Class B**
21	Colonic cytology sampling set	A collection of non-sterile devices intended to collect exfoliated colonic cells (colonocytes) from the surface of human rectal mucosa for colorectal cancer investigation and/or patient screening.	**Class B**
22	Computer vision/Machine learning-aided software application for cancer detection	A standalone software application intended to be used to scan radiological images (X-ray, CT scan, etc.) in order to screen/diagnose for cancerous tissues using machine learning-based training models and computer vision.	**Class C**
23	Coronary artery brachytherapy system applicator, manual-afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a manual-afterloading brachytherapy system. It is introduced into the patient and subsequently connected to the brachytherapy system source transfer device; it includes radiopaque markers to monitor the position of the radiation source. Disposable devices associated with the procedure may be included (e.g., syringe, connectors). This is a single-use device.	**Class D**
24	Cryosurgical set	A sterile collection of disposable devices used in conjunction with a cryosurgical unit as well as monitoring and other devices to perform a surgical technique that involves freezing a targeted area of tissue to damage and destroy cancer cells in the unwanted portions.	**Class C**
25	Electro cancer therapy system	An assembly of devices designed for the treatment of tumours and the destruction of their cancerous cells using low-voltage direct current of small intensity delivered via electrodes placed across the affected body area.	**Class C**

S. No.	Device name	Intended use	Risk Class
26	Electronic clinical breast examination system	A portable assembly of devices designed to electronically measure, map, document and store information about breast lesions/masses with regard to shape, size, location, consistency/relative hardness during a clinical breast examination (CBE).	**Class B**
27	Electroporation therapy system	A mobile assembly of devices designed to apply electrical impulses to the tissue to enable electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)] and genetic materials [electrogenetherapy (EGT)], to reach the cytoplasm.	**Class C**
28	Electroporation therapy system endoscopic applicator	A sterile, patient-contact component of an electroporation therapy system intended to fit onto the distal tip of an endoscope and connect to an electroporation therapy system generator to deliver electrical impulses to tissues during endoscopy as part of electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)], to reach the cytoplasm.	**Class C**
29	Embolization particle, bioabsorbable	A bioabsorbable, implantable bead/microsphere intended to be used to temporarily occlude an artery supplying hyperplastic/neoplastic tissue in a variety of anatomies (e.g., liver, lung, breast, bladder, uterus, head or neck); it does not include a pharmaceutical agent. It may be used independently to create ischemia in the tissue, or as an adjuvant in combination with cytostatic agents and other antitumour drugs to help optimize intra-tumour drug accumulation for interventional radiology and visceral surgery procedures. It is typically available as an injectable solution containing numerous microspheres [e.g., degradable starch microspheres (DSM)].	**Class D**
30	Embolization particle, non-bioabsorbable	A non-bioabsorbable, implantable bead/microsphere intended to be introduced into the peripheral vasculature during an interventional radiology procedure to treat hypervascularized tumours and arteriovenous malformation in a variety of anatomies (e.g., head, neck, spine, liver, genitourinary tract, uterus, gastrointestinal, limbs and lungs). It is typically available as injectable solution containing numerous microspheres [e.g., compressible polyvinyl alcohol (PVA) microspheres] intended to permanently obstruct blood flow to the tumour/malformation.	**Class D**

S. No.	Device name	Intended use	Risk Class
31	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	**Class C**
32	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].It is used for the screening of colorectal cancer and the detection of other diseases of the lower GI tract. This is a single-use device.	**Class B**
33	Extravascular-circulation hyperthermia system	An assembly of devices designed to produce and control heated fluids circulated within a vessel applied to the body (e.g., vest, mattress, jacket, band, pad, body wrap, catheter, probe) for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions.	**Class B**
34	Extravascular-circulation hyperthermia system applicator, extracorporeal	A vessel applied to the outside of the body (e.g., in the form of a jacket, vest, body wrap, cushion, blanket, or mattress) that incorporates tubing through which heated fluids are circulated for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator typically includes a thermometry component that monitors the temperature of the applicator during operation. The applicator includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a reusable device.	**Class A**
35	Extravascular-circulation hyperthermia system applicator, intracorporeal	A component of a hyperthermia system that typically consists of catheter-enclosed tubing which is introduced into the body either manually or endoscopically. Heated fluid is circulated through the applicator's tubing for localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator (also called an interstitial applicator or probe) typically includes a thermometry component that monitors the temperature of the applicator during operation; it also includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a single-use device.	**Class C**

S. No.	Device name	Intended use	Risk Class
36	Facial prosthesis	An externally-applied device intended to be used as an artificial substitute for parts or sections of the face [e.g., nose, eye(s), eye brows, upper lip] to help restore facial appearance. The device may be customized to meet the patient's needs and may be held in position with magnets or screw-like implants embedded into the patient's facial bone. It is used in cases of severe facial disfigurement typically caused by trauma (e.g., gunshot wounds) or major facial cancer surgery.	**Class B**
37	Fixed-aperture therapeutic x-ray system collimator	A non-automated, x-ray beam-limiting device that is a component of a therapeutic x-ray system and whose opening size/length/shutter assembly is fixed. It is used in radiation therapy applications to limit the effects of scattered radiation and to protect the patient by limiting or eliminating exposure to non-target body areas during treatment. This device is specifically designed for use with an x-ray simulation or therapeutic x-ray system.	**Class C**
38	Flexible fibre optic bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	**Class B**
39	Flexible fibre optic mediastinoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the mediastinum (the intrapleural space located behind the sternum). It is inserted into the body through an artificial orifice created by an incision made during mediastinoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to examine structures such as lymph nodes during a staging evaluation of lung cancer, or to establish the diagnosis of a tumour that is localized to the mediastinum. This is a reusable device.	**Class C**

S. No.	Device name	Intended use	Risk Class
40	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device typically through a fibre optic bundle or a video system, and an ultrasound probe. The probe may be built-in or inserted through a dedicated lumen so that its distal tip is positioned adjacent to that of the endoscope. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	**Class B**
41	Flexible video bronchoscope, reusable	An endoscope with a flexible inserted portion for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by a video system with a charge-coupled device (CCD) chip at the distal end and the images showing on a monitor. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	**Class B**
42	General-purpose infusion pump, mechanical, reusable	A non-electric, mechanically-powered (e.g., a spring mechanism) device designed for the continuous or intermittent infusion of medication, typically for antibiotic therapy, chemotherapy, or pain management by intravenous (IV), subcutaneous, intramuscular, or epidural routes. It is primarily designed to be worn by the patient during ambulation in the home. It may be used for patient-controlled analgesia (PCA), and may include mechanical indicators for flow and fluid level status. This is a reusable device.	**Class C**
43	General-purpose infusion pump, mechanical, single-use	A portable, non-electric, mechanically-powered device designed to be operated by healthcare professionals for dispensing a single dose of fluid medication (e.g., for antibiotic therapy, chemotherapy, analgesia). It consists of an empty reservoir intended to be filled with medication, a flow-rate regulator and a non-sterile (sterilizable) administration line intended to be connected to an infusion catheter (not included) for intravenous (IV), subcutaneous, intramuscular, or epidural administration. It may include flow and fluid level mechanical indicators and may be worn by the patient in and outside of healthcare settings. This is a single-use device.	**Class C**

S. No.	Device name	Intended use	Risk Class
44	Hyperthermia system temperature probe	A device (a probe) intended to be used exclusively to monitor tissue or body temperature during hyperthermia treatments. Depending on the kind of hyperthermia system it is used with, e.g., ultrasound, radio-frequency (RF) or microwave, this probe is shielded in such a way that its operation is not affected by the energy from the hyperthermia applicator(s) in use during the treatment. This is a reusable device.	**Class C**
45	Implantable Vascular port/catheter	A fully-implantable device assembly intended to provide access to arteries/veins (excludes coronary and intracerebral circulation) for infusion (e.g., chemotherapeutic agents, blood transfusions) and/or drainage (e.g., blood). It consists of: 1) a subcutaneous chamber, with a self-sealing puncturable septum for percutaneous insertion of a hypodermic needle; and 2) an attached catheter which passes into the arteries/veins.	**Class C**
46	Intracavitary-circulation hyperthermia system	An assembly of electrically-powered devices designed to continuously lavage body cavities (e.g., pleural cavity, peritoneal cavity, bladder lumen) with warmed fluids/chemotherapeutic agents to raise the local temperature and/or enhance the effect of drugs, typically in the treatment of malignancy. It typically includes a water heater/cooler, fluid pump, controls, inputs for monitoring temperature, a circuit with heat exchanger, fluid reservoir, and tubing connectors. Introduction/drainage catheters are connected to the system and placed in the body cavity.	**Class C**
47	Intraoperative gamma radiation detection system probe, reusable	An electrically-powered, invasive component of an intraoperative gamma radiation detection system intended to be introduced into the body during a surgical procedure to detect and quantify gamma radiation emitted from previously-administered radiopharmaceuticals (e.g., localized in sentinel lymph nodes), in conjunction with a dedicated control unit (not included). It is typically manipulated using surgical forceps and incorporates a crystal scintillator and photomultiplier. This is a reusable device.	**Class C**

S. No.	Device name	Intended use	Risk Class
48	Intraoperative tumour margin fluorescence imaging system	A set of devices designed for the excitation of an injected fluorophore (e.g., pegulicianine), and subsequent imaging of the illuminated area, to allow for intraoperative detection of residual cancerous tissue in the resection cavity following removal of the primary specimen during surgical procedure (e.g., lumpectomy). It includes a probe, a handpiece with an optical component including a digital camera which is inserted into the cavity for image capture, and a cable which includes a connection to the computerised system and a fibre optic light guide. This is a reusable device.	**Class C**
49	Intravascular/intracavitary-circulation hyperthermia system	An assembly of devices designed to circulate warmed fluids or autologous blood through the vasculature or cavity of a targeted anatomical area (e.g., peritoneal/pleural cavities, thorax, abdomen, section of a limb) to treat cancer. It is typically computer-controlled and consists of pumps, heat exchanger, valves, detectors/sensors, clamps, monitors, alarms, disposable tubing/filtration set and oxygenator. It heats the blood/fluids to temperatures up to 43 °C to enhance the effect of drugs [e.g., for intraperitoneal hyperthermic chemotherapy (IPHC)] and help destroy cancer cells.	**Class C**
50	Intravascular/intracavitary-circulation hyperthermia system set/Kit for hyperthermic perfusion	A collection of sterile devices used with an intravascular/intracavitary-circulation hyperthermia system for the circulation of blood/fluid between the patient and the system's extracorporeal circuit during cancer therapy. It typically consists of drains/catheters, tubing, connectors, manual clamps, and hard or soft reservoirs; some types may include in-line filters, an oxygenator, and temperature sensors. This is a single-use device.	**Class C**
51	Microwave ablation system	An assembly of devices consisting of a generator and a probe (and other accessories) intended to generate and transmit microwave energy for localized non-vascular soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia. The generator connects via a delivery cable to a probe for delivery of microwaves to the target tissues. It is intended to be used in percutaneous, laparoscopic, natural orifice or open surgery procedures to ablate tissue typically in the liver, lung, pancreas, kidney, and uterus (e.g., endometrial ablation).	**Class C**

S. No.	Device name	Intended use	Risk Class
52	Microwave ablation system generator	A mains electricity (AC-powered) device intended to generate microwave energy for localized non-vascular soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia (excludes cerebral and coronary tissues). The generator connects via a delivery cable to a probe (not included) for delivery of microwaves to the target tissues. It is intended to be used in percutaneous, laparoscopic, natural orifice or open surgery procedures to ablate tissue typically in the liver, lung, pancreas, kidney, and uterus (e.g., endometrial ablation).	**Class C**
53	Microwave ablation system probe/microwave ablation antenna	A hand-held surgical instrument designed to connect to a microwave ablation system generator to deliver microwaves to a targeted operative site for localized soft-tissue ablation, typically to treat tumours, hydatid cysts and/or menorrhagia. The device is intended to be used in percutaneous, endoscopic [e.g., gastroscopic, laparoscopic], natural orifice or open surgery procedures to ablate tissues (e.g., endometrial ablation).	**Class C**
54	Microwave hyperthermia system	A mains electricity (AC-powered) device assembly designed for controlled heating (i.e., temperatures above 43° Celsius) of the body using microwaves, for the treatment of malignant or benign tumours or other disease conditions [e.g., benign prostatic hyperplasia (BPH), prostatitis]. It includes a microwave generator, controls, software (e.g., treatment planning software) and a microwave applicator. It is intended for both whole-body and localized heating of tissues/organs through either externally-mounted components or from catheter- or probe-type applicators inserted topically, endoscopically, or surgically.	**Class C**
55	Microwave hyperthermia system applicator, extracorporeal	A component of a microwave hyperthermia system designed to direct and deliver microwave energy used to produce a systemic or local heating effect. It is typically mounted on a floor, wall, or ceiling suspension that allows the operator to position the microwave source from a point outside the patient's body. The applicator assembly includes cables and connectors that interface with the energy-generating unit of the hyperthermia system during treatments.	**Class C**

S. No.	Device name	Intended use	Risk Class
56	Microwave hyperthermia system applicator, intracorporeal	A component of a microwave hyperthermia system designed to be placed inside the body to deliver microwave energy to produce a systemic or local heating effect. It is also referred to as an interstitial applicator or probe and is typically a catheter-enclosed conductor of microwave energy that is introduced into the body either manually or endoscopically. It typically includes a thermometry component that monitors the temperature of the device during operation.	**Class C**
57	Microwave/electrosurgical system generator	An electrically-powered component of a microwave ablation/electrosurgical system intended to generate both: 1) radio-frequency (RF) electrical current; and 2) microwave energy for subsequent cutting, coagulation, and ablation of soft tissues during an endoscopic or open surgical procedure; it is not dedicated to focal ablation of specific tissues. It is not intended for inert gas electrosurgery.	**Class C**
58	Multi-modality hyperthermia system	A mains electricity (AC-powered) device assembly designed for controlled heating (i.e., temperatures above 43° Celsius) of the body using multiple energy sources, for the treatment of malignant or benign tumours, or other disease conditions (excludes cerebral and coronary tissues). It includes a patient-end applicator, software, and a multi-modality generator(s)/control unit. It is intended to achieve whole-body and localized heating of tissues using two or more energy sources [e.g., ultrasound, radio-frequency (RF), microwave, circulating heated fluid] through either externally-mounted components, or from catheter- or probe-type applicators inserted endoscopically or surgically.	**Class C**
59	Photopheresis system blood set	A collection of devices used as part of a photopheresis system for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). It typically consists of tubing (patient and fluid lines), fluid/blood component bags, a dedicated centrifuge bowl, a photoactivation chamber, connectors, and clamps. It conducts blood from the patient to the system's main unit, aids in blood processing, and returns leukocyte-enriched and untreated components of the blood after irradiation. This is a sterile, single-use device.	**Class C**
60	Photopheresis system lamp assembly	An assembly of ultraviolet A (UVA)-emitting tubular strip lights that is an exchangeable component of a photopheresis system, and used to irradiate blood components during extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL).	**Class C**

S. No.	Device name	Intended use	Risk Class
61	Polymer-metal oesophageal stent	A non-bioabsorbable, expandable, tubular device intended to be implanted into the oesophagus to maintain luminal patency in strictures and prevent tumour in-growth. It may also be intended to seal oesophageal fistulas, reduce acute bleeding from oesophageal varices, and/or to treat other lesions causing oesophageal leakage (e.g., anastomotic). It is typically expanded in situ (e.g., self-expands) and disposable devices intended to assist implantation may be included.	**Class C**
62	Radiation therapy digital imager	An automated device that is typically mounted on the gantry of a linear accelerator and intended to produce digital images of x-rayed anatomical landmarks to guide radiation treatment (e.g., tracking/targeting tumours). The device may be a digital imaging panel (e.g., of silicon) on robotic arms; it may also have an x-ray source to generate higher quality images.	**Class C**
63	Real-time position management respiratory gating system, optical/Respiratory gating system, radiation procedure	An assembly of electronic devices designed to track the respiratory pattern of a patient by means of optical technology to correlate tumour position with the respiratory cycle during radiation treatment planning, radiotherapy, computed tomography (CT) imaging, or other radiation procedures. It provides real-time position management (RPM) and involves optical-based tracking (e.g., video, infrared, laser) of the respiratory cycle to enable irradiation control during the procedure. It may include a tracking camera connected to a dedicated personal computer workstation and a reflective chest wall/abdominal marker.	**Class C**
64	Robotic Guidance system for image Guided procedures	It is an accessory to an imaging system (CT, CT-PET) intended for the spatial positioning and orientation of an instrument guide. A surgeon then manually advances one or more instruments for percutaneous image guided interventional procedures through the instrument guide. The device is not intended to make any contact with the patient.	**Class B**
65	Scalp cooling system, hair loss	An assembly of electrically-powered devices intended to reduce scalp hair loss associated with intravenous chemotherapy treatment by cooling the scalp to cause vasoconstriction and reduction of chemotherapy drug uptake by the follicular cells. It consists of a control unit which pumps a cooling agent to a head-worn cap containing coolant channels and temperature monitoring sensors. An insulating cap (e.g., neoprene) may be worn over the cooling cap to secure it and prevent condensation.	**Class B**

S. No.	Device name	Intended use	Risk Class
66	Stereotactic radiosurgery system for central nervous system (CNS)	A set of devices that are designed to uses very precise beams of gamma rays to treat an area of disease (lesion) or growth (tumor), especially in the brain, upper spine and in certain cases, vascular abnormalities.	**Class D**
67	Teletherapy radionuclide system table, powered	A device that is a component of a teletherapy radionuclide system (commonly known as a cobalt therapy machine) and that is a powered/programmable table specifically designed to position and support a patient during treatments administered using a therapeutic radionuclide teletherapy system (e.g., a Cobalt-60 teletherapy system). It has electronic and/or software controls for table top height and positioning. It can be a stationary or mobile unit, or incorporated as an integral component of a radionuclide teletherapy system or gantry configuration.	**Class B**
68	Teletherapy radionuclide system, conventional/Cobalt therapy machine	A stationary assembly of computer-based devices designed to deliver a therapeutic radiation dose to an anatomical region from a single external radiation beam produced by a radionuclide source, typically to treat malignant tumours; it does not provide image-guided radiation therapy (IGRT) functionality during treatment delivery.	**Class C**
69	Telethermographic system	A telethermographic system intended for adjunctive diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.	**Class A**
70	Therapeutic oncological/gynaecological ultrasound system (High intensity focused ultrasound (HIFU) ablation system)	An assembly of electrically-powered devices designed to treat solid tumours of hard (bone) and/or soft tissue [e.g., liver, kidney, breast, prostate] and/or gynaecological disorders (e.g., uterine fibroid, adenomyosis) through noninvasive or non-surgically invasive localized application of high intensity focused ultrasound (HIFU) or high intensity therapeutic ultrasound (HITU) intended to gradually denature/ablate tissue lesions. Optimal patient positioning is achieved using an ultrasound scanner or MRI system.	**Class C**

S. No.	Device name	Intended use	Risk Class
71	Tumour-therapy radio-frequency hyperthermia system	A mains electricity (AC-powered) device assembly designed for controlled heating (i.e., temperatures around 43° Celsius) of the body using radio-frequency (RF) energy, for the treatment of malignant or benign tumours, or other disease conditions; it is not intended for direct tissue ablation. It is intended for both whole-body and localized heating of tissues/organs through either externally-mounted components or from catheter- or probe-type applicators inserted topically, endoscopically, or surgically.	**Class C**
72	Tumour-therapy radio-frequency hyperthermia system applicator, intracorporeal	A component of a radio-frequency (RF) hyperthermia system designed to be placed in the body to deliver radio-frequency (RF) energy to produce a systemic or local heating effect for the treatment of malignant or benign tumours, or other disease conditions. It is also referred to as an interstitial applicator or probe and is typically a catheter-enclosed conductor of RF energy that is introduced into the body either manually or endoscopically. This is a single use device.	**Class C**
73	Ultrasonic hyperthermia system/Ultrasonic ablation system	An assembly of devices designed to produce and control the delivery of high heat (i.e., temperatures greater than 43 deg Celsius) to the body using ultrasonic energy for the intracorporeal or extracorporeal treatment of malignant or benign tumours, or other disease conditions. Energy delivered to the patient is from either an externally-mounted transducer or a transducer-containing catheter or probe used topically or inserted endoscopically or surgically. It is not intended for physiotherapy applications.	**Class C**
74	Ultrasound hyperthermia system transducer, extracorporeal	An ultrasound (US) transducer assembly that is a component of an ultrasound hyperthermia system used to induce systemic or local body heating of sufficient magnitude to create a targeted therapeutic effect. It is mounted within the gantry or housing of the hyperthermia system or mounted on a floor, wall, or ceiling suspension that allows the operator to position the transducer assembly external to the patient during treatment.	**Class C**
75	Ultraviolet Extracorporeal Photopheresis system	An assembly of devices used for extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL). It irradiates the leukocyte-rich fraction of peripheral blood by UVA radiation extracorporeally and returns back the treated and untreated blood to the patient. This system may or may not use a UV-active drug (either ingested by patient or injected into the leukocyte-rich fraction of the extracted peripheral blood)	**Class C**

Name of Category:

Class A (non-sterile and non-measuring) medical devices

Total No. of Devices:

803

List of Class A (Non-sterile and non-measuring) medical devices (other than In-vitro diagnostic (IVD) medical devices)

S.No.	Device Name	Intended Use
1	Abdominal support/belt/binders, reusable	Intended to hold abdominal muscles together to relieve pain and increase circulation at surgical site to promote healing and decrease swelling. May also make physical activity more comfortable.
2	Abdominal support/belt/binders, single use	Intended to hold abdominal muscles together to relieve pain and increase circulation at surgical site to promote healing and decrease swelling.
3	Abrasive polishing agent	A substance, or combination of abrasive substances (e.g. silica pumice), intended to be used for cleaning the accessible surfaces of the teeth by polishing. It does not contain medication and used by dental professionals.
4	Absorbent cotton wool	Intended to used for applying medication to, or absorbing small amounts of body fluids
5	Accupressure calf band	Intended to wear around the calf to apply pressure to an acupressure point to relieve low back pain, including sciatica and piriformis syndrome.
6	Accupressure wristband	Intended for the application of pressure to the Nei-kuan (P6) acupressure point on the wrist, the area identified to help relieve the sensation of nausea.
7	Acoustic chamber for audiometric testing	Intended for use in conducting diagnostic hearing evaluations, while eliminating sound reflections and providing isolation from outside sounds.
8	Acoustic Stethoscope	A mechanical listening device used for listening to sounds from the heart and lungs and their qualitative assessment.
9	Activated-medium surgical warming blanket	A non-sterile device intended to help prevent a patient from cooling prior to, during, and after a surgical intervention by serving as a heat-generating cover.
10	Acupressure applicator, reusable	Applied to the skin without insertion into the body to apply pressure and/or friction to acupressure points.
11	Acupressure applicator, single-use	To be used for acupressure treatment at home by applying non-invasive pressure to acupuncture points. Applied to the skin without insertion into the body.
12	Acupuncture unit, home use	It is intended to provide mild and temporary stimulation of accupressure points resulting in improvement of energy flow and overall vitality.

S.No.	Device Name	Intended Use
13	Adaptor, light source	Intended to permit the connection of the devices that together deliver light to a work field from a light source.
14	Adaptor, luer	Adapters which connect or stopper enteral feeding tubes.
15	Adhesive felt pad	Intended to offload pressure from ulcer areas, recurrent plantar ulcers, calluses and corns
16	Adhesive plaster (Zinc oxide adhesive plaster)/Tape	It is intended to secure dressings and for strapping on intact skin.
17	Adhesive strip	A flexible strip (of fabric, plastic, paper, or other material) coated on one side with a pressure-sensitive adhesive, typically used to cover or approximate the edges of superficial wounds or fix dressings to skin. The device may include an adhesive pad and have qualities such as waterproof.
18	Adhesive tape remover	Help reduce pain and ease removal of medical adhesives used in stoma care products, dressings and other medical appliances from the skin surface
19	Adult Diaper/Under Pad	Intended to be used by an incontinent patient's for absorbing excreta (e.g, urine, etc.). It may be intended for home-use or/and hospital settings.
20	Aerosol adhesive for compression garments	A sticky substance that is applied on the skin to anchor compression garments in place.
21	Aerosol delivery tubing	A flexible tube used in conjunction with an oxygen mask, endotracheal (ET) tube, humidifier, or nebulizer, intended for the delivery of aerosolized humidification, typically oxygen enriched.
22	Air cushion/Pressure relief cushions	Intended to relieve pressure on an affected area when a person has hemorrhoids or when he has undergone surgery in the back or buttock area/prevention of pressure sores/ulcers in patients
23	Airway device cleaning utensil	A hand-held device intended to be used to clean an in situ airway device (not disinfection). It can also be used to clean an airway device ex situ (i.e., once it has been removed from the patient).
24	Airway protection face mask	Intended to provide respiratory protection

S.No.	Device Name	Intended Use
25	Airway tube forceps, reusable	Used for grasping a tube for its insertion and/or extraction into/from the airways, or for grasping obstructive objects for their removal from the airways.
26	Alarm, bed occupancy	Bed Floor Mat/Crash Mat Alarm/Alert Patient Movement
27	Allergy testing adhesive strip, epicutaneous	A band of adhesive material designed to be used for epicutaneous allergy testing.
28	Alternating-pressure bed mattress overlay, reusable	A pad or thin mattress, usually full-body length, which is placed on top of a bed mattress and designed with parallel chambers that are alternately filled with forced-air to actively change an occupant's bed contact points, typically to relieve pressure points for comfort and to prevent pressure sores. It is commonly used for elderly immobilized (especially in cases of decubitus ulcers), patients with disabilities, or patients with low body fat. This is a reusable device.
29	Alternating-pressure bed mattress overlay, single-use	A pad or thin mattress, usually full-body length, which is placed on top of a bed mattress and designed with parallel chambers that are alternately filled with forced-air to actively change an occupant's bed contact points, typically to relieve pressure points for comfort and to prevent pressure sores. It is commonly used for elderly immobilized (especially in cases of decubitus ulcers), patients with disabilities, or patients with low body fat. This is a single use device.
30	Alternating-pressure bed mattress system	An alternating pressure system designed to be used on top of a bed to provide therapeutic or protective effect.
31	Amsler grid	Intended to rapidly detect central and paracentral irregularities in the visual field.
32	Anaesthesia catheter Luer connector	Intended to create a mechanical union between an anaesthesia catheter and an external device
33	Anaesthesia depth simulator	intended to simulate the electroencephalography (EEG) signals of an unconscious patient
34	Anaesthesia instrument table	It is intended as a support for Anaesthesia instruments used during general anaesthesia surgical procedures.

S.No.	Device Name	Intended Use
35	Anaesthesia mask stabilizer	A device intended to secure an anaesthesia mask on the face of a patient typically by providing anchorage for the fixation of the mask's headstrap.
36	Anaesthesia mask stabilizer, single-use	Accessory to anesthesia face mask to assist in locating the mask headgear (strap) to the mask.
37	Anaesthesia system leakage tester	A device intended to test an anaesthesia system for leakage.
38	Anaesthesia tube holder	The intended purpose for this device is for holding and supporting respiration tubing and breathing circuits connected to a patient, to prevent disconnection.
39	Anaesthesia warmer	A device intended to warm the anaesthetic solutions prior to it being administered to a patient for anaesthesia.
40	Anaesthetic gas scavenging terminal unit	A device intended to function as an outlet assembly to which the operator can connect/disconnect an anaesthetic gas scavenging system (AGSS).
41	Analytical non- scalp cutaneous lead	Intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and a device designed for electrophysiological recording/monitoring [e.g., electromyography (EMG), evoked potentials (EP), bioelectrical impedance].
42	Analytical non-scalp cutaneous electrode	Electrical conductor designed to be attached to the skin surface of a patient outside of the hair line (i.e., non-scalp) to conduct electrical signals to a parent device for electrophysiological recording/monitoring.
43	Analytical non-scalp cutaneous lead	Intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and a device designed for electrophysiological recording/monitoring [e.g., electromyography (EMG), evoked potentials (EP), bioelectrical impedance].
44	Anatomical training model	A 3-D printed patient specific model of an organ (e.g., heart, kidney, lung) or bone(s) intended to be used to assist peri-operative anatomical visualisation and surgical treatment planning. It is created using 3-D Printing processes based on patient medical images.
45	Anesthesia face mask, reusable	A device designed to be placed over a patient's nose and/or mouth to administer anaesthetic gases to the upper airway.

S.No.	Device Name	Intended Use
46	Anesthesia face mask, single use	A device designed to be placed over a patient's nose and/or mouth to administer anaesthetic gases to the upper airway.
47	Ankle binder, reusable	A strip or roll of fabric or plastic material designed to be wrapped around the ankle to help stabilize and support the joint.
48	Ankle cap	Intended to provide mild compression & support to the ankle joint and to manage ankle pain and inflammation.
49	Ankle sleeves/brace	Intended as the external supports to limit certain motions, such as plantar flexion/inversion and manage postoperative/posttraumatic pain
50	Ankle traction belt	Intended to immobilize the ankle and adjoining joints after injury / surgery to support fast healing and prevents further damage and also helps to decrease pain, spasms and swelling.
51	Ankle/foot orthosis	A prefabricated (non-customized) externally applied and wearable appliance or apparatus intended to encompass the ankle joint, or the ankle and foot, to support, align, prevent, or correct orthopaedic deformities/injuries or to improve function of the ankle and/or foot through actions such as alignment, hinge-support, or dorsiflexion assistance.
52	Ankle/foot orthosis	A prefabricated externally applied and wearable appliance or apparatus intended to offload and redistribute foot pressures that affect pedal circulation to improve blood flow and help heal diabetic foot ulcers or postsurgical wounds.
53	Anomaloscope	Intended to test a patient for abnormal red/green colour vision by differentiating the red/green colour vision defects.
54	Anterior chamber physical simulator	Designed to mimic the fluid dynamics in the anterior chamber of the eye during priming/calibration of a phacoemulsification system irrigation/aspiration pump.
55	Anterior wedge footwear/Off loading shoes	Intended for offloading the pressure from forefoot to heel after correction of conditions such as Hallux Valgus, Hammer Toes, Tailors Bunions and Ulcers of the forefoot
56	Antimicrobial postsurgical brassiere	Intended to support and/or contour the breast(s) or hold a dressing in place after surgical intervention (e.g. thoracic surgery, mastectomy, lumpectomy). May be used to prevent the formation of oedema and to support venous return and lymphatic drainage.

S.No.	Device Name	Intended Use
57	Antimicrobial postsurgical female underpants	It is intended for use during medical treatment (e.g., chemotherapy) or be used to protect the skin following treatment with a medication (e.g. ointment, cream).
58	Anti-shock body support/Garment	Intended to prevent excessive blood loss and prevent post partum haemorrhage complications.
59	Anti-tremor gyroscopic orthotic glove	A battery-powered device designed to be worn on the hand/forearm of a patient with hand tremors [e.g., due to Parkinson's disease, Essential tremor (ET)] to reduce tremors and facilitate activities of daily living using the hand. It is in the form of a glove with forearm sleeve and built-in gyroscopes which generate tremor-countering forces to promote hand stabilization.
60	Arm board pad	It is intended to provide support to the patient's arm during prolonged surgeries.
61	Arm board, pediatric	This medical device is intended to immobilize and hold steady infants' limbs when securing intravenous lines.
62	Arm prosthesis socket	A device that fits over the terminal end of a residual upper limb and serves as an interface between the limb and an artificial replacement arm segment (prosthesis).
63	Arm prosthesis, pediatric	Artificial hand or arm prosthesis for physically disabled pediatric patients.
64	Arm sling	Intended to immobilize the arm, by means of a fabric band suspended from around the neck.
65	Arm/leg procedure positioner padded strap	To protect the patient's foot/leg in stirrups.
66	Artificial airway stylet	A device intended for insertion within the lumen of an artificial airway tube to stiffen and/or maintain the shape of the tube to facilitate intubation.
67	Assistive ergonomic chair mobility base	Intended for use as a support to an assistive ergonomic chair used by a healthcare provider/carer to provide mobility for a disabled (often paediatric) patient.

S.No.	Device Name	Intended Use
68	Assistive ergonomic chair, electrically-adjusted	An electrically-powered device intended to support and position a patient (disabled and/or discomforted) in a sitting posture while performing activities of daily living, including work-related activities and to provide improved personal body posture and/or to help prevent/reduce physical problems associated with poor mobility or sedentary lifestyle. It is not a wheelchair
69	Assistive foot-propelled bicycle	A therapy bike designed for children and teenagers with neuromuscular diseases permitting independent mobility, assisting physiotherapist treatments, providing training for support and balance reactions as well as movement coordination.
70	Assistive gripping/twisting tool, reusable	The devices are handheld grips with attached wristbands intended for stimulation of the sensory neuronal network (hand/fingers) as part of therapies for patients suffering from neurodeneration such as ASD, ADHD and Parkinson's, or other nervous issues.
71	Assistive shoes/boots	It is a shoe attachment that is primarily intended to assist people with Parkinson’s to overcome a symptom called Freezing of Gait (FOG) through visual cueing by providing visual cues in the form of laser lines. It can act as an intervention for falls prevention in the Parkinson’s population.
72	Atomizer	A device that is intended to provide liquid medication in aerosolized form into the air that a patient will breathe.
73	Attention assistive training device	A device designed to be used by a person with a disorder to develop their attention ability to select, focus, control and inhibit.
74	Automated perimeter	Intended to be used to measure the visual field of the eye.
75	Back Support/Brace	Intended to prevent unnecessary movements and pain that may further damage the back and to help in alignment of spine and strengthening of back muscles.
76	Bagolini lens	Intended to determine harmonious/anomalous retinal correspondence.
77	Balance Board	Intended to train patient with difficulties in balance (proprioreception) (e.g. a paraplegic or a stroke patient)

S.No.	Device Name	Intended Use
78	Balance/mobility management system	This device uses sensors to determine the centre of pressure and postural sway of an individual during standing for balance management.
79	Bandage scissors, reusable	Heavy scissors for cutting pads, plaster and plastic rail associations.
80	Bar dental precision attachment	It connects removable partial dentures to fixed bridgework under a male/female locking mechanism.
81	Basket stretcher	Intended to transfer patients in emergency situations such as in the mountains, and marine offshore application.
82	Bed board	A flat, stiff device designed to increase the firmness of a hospital bed's mattress to provide an appropriate rest surface for the user typically with spinal problems.
83	Bed exit monitor, fall prevention	Intended to be placed under mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.
84	Bed traction frame	Intended to provide overhead support framing for hospital beds to assist in the treatment and movement of bed patients
85	Bedrail pad	Intended to protect the patient from coming into contact with the bedrails and inadvertently hurting or injuring themselves.
86	Bicycle exerciser	Device is used by patients in a physical therapy setting under the direction of a medical professional for passive, assisted & active training of upper and low limbs during rehabilitation, to improve motor function.
87	Binocular loupes	It is intended for viewing details of objects with some magnification during ophthalmic/dental and other examinations and surgeries
88	Biofeedback system for rehabilitation	A system, comprising of wearable motion capture devices that allows patients with upper and lower extremity movement dysfunction to undertake intensive practice of single and multi-joints using movement biofeedback. The system detects movement and provides this as feedback to the patient. This does not display a quantifiable property in measuring units.
89	Birthing bath	Intended to be filled with heated water for use before and/or during child birth and to provide a comfortable environment for the expecting mother prior to birth.
90	Birthing bed/table, non-powered	Intended to be used as a support surface during labor and delivery.

S.No.	Device Name	Intended Use
91	Birthing bed/table, powered	Intended to be used as a support surface during labor and delivery.
92	Bite block, dental	A non-sterile device inserted into a patient's mouth for the prevention of oral tissue damage (e.g., the teeth, lips, tongue and buccal mucosa) and to allow them to bite down on for greater comfort during a dental procedure. This is a reusable device.
93	Bite block, endoscopy	A single use accessory used to protect both the patient and the endoscope, when an endoscope is inserted into a patients mouth for a procedure. It may also be used during other treatments such as intubation of a tracheal tube.
94	Bite block, radiotherapy	Bite Blocks are devices which are used to reproducibly position the mouth, tongue or lips during radiotherapy treatment of the head and neck.
95	Bite registration rim wax	A dental material (modelling wax) with or without reinforcing foils (metal, polymer) for registration of jaw relation (making bite rims).
96	Bite relief pad	Intended to help relieve pain or discomfort after orthodontic treatment by placement between the upper and lower sets of teeth and bitten down on.
97	Blood/body fluid solidifier	A solidifier substance is intended to be used to absorb and solidify blood and/or other body fluids collected in surgical suction canisters. The substance is often added to the bottle/canister before or after collection of the fluid.
98	Bobath table	Intended for postural exercises, rolling, turning and balance training of patients with loss of sensation or poor balance and other neurological conditions such as stroke, head injury and orthopedic indications
99	Body arch traction table	Intended to support the body of a patient and provide traction for the back muscles and spine by flexing the patient into a reverse supine body arch
100	Body waste receptacle	Intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.
101	Brachytherapy radionuclide phantom, test object	Intended to mimic the functional/physical characteristics of normal or diseased human organs during performance evaluations of brachytherapy system

S.No.	Device Name	Intended Use
102	Breast binder	A non-sterile device intended to be applied to the breast or breasts for soft tissue support or securing a dressing in place after surgical procedures.
103	Breast pad	Used to absorb excess milk and protect the breast during nursing.
104	Breathing circuit bag/Reservoir bag	A device intended to store breathing gas during the respiratory cycle.
105	Breathing circuit condenser	Intended to be integrated within the expiratory limb of a breathing circuit to remove excess moisture through cooling and condensing, whilst also reheating the dried gases to an appropriate machine-compatible temperature.
106	Breathing circuit dryer	A device that is used for the purpose of drying breathing circuit equipment that have been washed in order to prevent bacteria growth and deterioration.
107	Breathing mouthpiece	A device intended to be inserted into a patient's mouth to facilitate access to the respiratory system.
108	Cable-controlled hand prosthesis	Intended as an artificial hand for physically disabled persons, whose movement can be controlled by a cable
109	Camera cover	Provide an infection-control protective barrier for dental intra-oral camera
110	Camera for dental use	Intended to be used to record that location of posts and or abutments in a lab model or the mouth allowing for a dental treatment plan to be produced during dental implant planning.
111	Camera for medical applications	A camera to be used with microscopes, colposcopes and on endoscopic procedures.
112	Canalith repositioning procedure chair, manual	A device intended to be occupied by a patient and manually operated by a healthcare professional to facilitate therapeutic physical manoeuvres of the patient’s head and trunk (accelerations and decelerations in a multiaxial plan) to treat balance disorders [e.g., benign paroxysmal positional vertigo (BPPV), canalithiasis] caused by displaced canaliths (otoconia) in the inner ear of the patient.
113	Capnography oxygen mask	A device intended to be placed over the nose and mouth to deliver oxygen (O2) to a patient's airway and to sample exhaled respiratory gases for monitoring the patient’s ventilatory status.

S.No.	Device Name	Intended Use
114	Capnography sampling adaptor	The device is intended for sampling CO2 and use with monitors enabled with capnography technology .
115	Cardiac compression board	A flat, rigid device that is placed under a patient to act as a support during cardiopulmonary resuscitation.
116	Cardiopulmonary resuscitation mask	A flexible, form-shaped device that is placed over a patient's mouth to administer "mouth-to-mask" exhaled air from the user to the patient during cardiopulmonary resuscitation (CPR).
117	Cardiopulmonary resuscitation mouthpiece/cover	A non-sterile device that consists of a mouthpiece with an integrated face/body covering sheet intended to be placed over a patient during cardiopulmonary resuscitation (CPR) to prevent cross-contamination between patient and CPR administrator. This is a single-use device.
118	Cast boot/shoes	A boot-like cover for a foot enclosed in a leg cast or bulky bandages intended to support postsurgical healing, injury/trauma care or any situation that requires a pressure off-load of the foot.
119	Cast removal protective tape	To be placed between a cast stockinette and the lining of a cast, along the line where subsequent cast cutting is intended to occur during cast removal, to prevent cuts and burns to the skin caused by the cast cutter/saw.
120	Cast stockinette	Intended to be used with casting material to provide under-cast padding and cushioning.
121	Cast walking heel	A rubber device designed to be attached to or incorporated into a cast to support the patient while walking.
122	Cerebral Cavernous Malformations (CAM) vision stimulator	Intended for stimulation of the eye for treatment of lazy/ambyopic eye
123	Cerebral Palsy (CP) walker	Intended as a walking aid for patients affected by cerebral palsy, for postoperative rehabilitation, polio, and other neurodevelopmental conditions
124	Cervical cytology scraper, reusable	Intended to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer.

S.No.	Device Name	Intended Use
125	Cervical pillow	Intended to provide support to people who have trouble keeping their spine straight and management of neck/cervical pain
126	Cervical spine collar	Intended to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains (often to treat whiplash resulting from an automobile accident).
127	Cervical traction head holder/head halter	Intended to be used with cervical traction kit to halt the head for physical support.
128	Cervical traction kit (with/without weights)	Intended for traction of cervical region in conditions such as neck or back pain, post surgery rehabilitation, reducing neck pressure, etc.
129	Cervical traction spreader bar/ Spreader bar	Intended to serve as a component of a traction kit to relieve pressure by stretching the musculature and connective tissue components of the cervical spine.
130	Cervicothoracic spine orthosis	Intended to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.
131	Cervicothoracolumbosacral spine orthosis	Intended to encompass the cervicothoracolumbosacral spine region of the neck and trunk.
132	Chair cushion, pediatric use	A supportive seat shell designed for use with a disabled child to allow them to sit independently on a chair/swing/shopping trolley
133	Chair, flotation therapy	Intended to aid in the prevention of pressure injuries as a result of reduced mobility and extended sitting postures.
134	Chemotherapy spill clean-up kit	Intended to safely clean and dispose of Chemotherapy drug spills.
135	Chest stand	Intended to provide a stable and adjustable platform to position patients for accurate and high-quality chest/full body X-ray examinations.
136	Chest/Limb Restrainer	Intended to stop or limit a patient's movement
137	Cholera bed	Intended as a physical suppport for severely ill and weak patients including those suffering from cholera
138	Circulating-fluid thermal therapy system	Designed to provide extended cold therapy to assist in a variety of applications as directed by a medical professional. It is designed not to be applied directly to the skin and is to be used as part of recovery from surgery either in the hospital setting or at home.

S.No.	Device Name	Intended Use
139	Clamp for rubber dam	A dental device with a buccal and lingual wing, or flange, used to anchor a rubber dam down to the cervical region of an exposed tooth.
140	Clavicle support/brace/belt	Intended to support and limit the movement of clavicle bone in case of injury, fracture, post surgery, etc.
141	Cognitive test equipment	Evaluation and training in stereognosis, form constancy, position in space, shape recognition and sequencing as well as teaching compensatory techniques for loss of visual field.
142	Cold compression therapy cervical spine collar	Intended to facilitate, through cooling and compression, the treatment of a variety of conditions resulting from injury/surgery to the neck region (e.g., inflammation, stiffness, whiplash).
143	Cold/cool therapy gel	Intended for localized topical skin application to provide a cooling effect for underlying muscles/joints to reduce pain and swelling.
144	Collar and cuff arm sling	Intended to immobilize forearm, elbow, humerus or shoulder injuries.
145	Colour discrimination non-prescription spectacles	A non-prescription ophthalmic device intended for use by people with color blindness to improve color discrimination and blocks UVA and UVB radiation from sunlight.
146	Colour discrimination tester	Intended to test a person's ability to differentiate between colours.
147	Colour-discrimination eye chart	Intended for testing colour vision.
148	Compression bandage: two component system	Intended for management/prevention of venous insufficiency, chronic oedema, venous ulcers, etc.
149	Compression/pressure sock/stocking applicator	Intended to assist in wearing/removing of medical compression stockings.
150	Compression/pressure tubular garment	To tightly fit over and apply compression/pressure (i.e., graduated or even-force) to a part of a limb, typically for the treatment/prevention of a disorder(s) of circulation [e.g., venous insufficiency, deep vein thrombosis (DVT)], to control scarring, and/or to manage lymphoedema.

S.No.	Device Name	Intended Use
151	Conductive abrasive gel for skin preparation	Designed to reduce the resistance (impedance) and defatting the skin in preparation for electrophysiological examinations: electroencephalography (EEG), long-term EEG monitoring, polysomnography (PSG), evoked potentials (EP), stress test ECG, ECG monitoring by Holter in clinics, hospitals, diagnostic centers
152	Conductive electrode gel/paste (adhesive/non-adhesive)	Intended to reduce resistance between skin and electrodes during examinations such as ECG, EEG, EMG
153	Congenital hip dislocation abduction splint	Intended to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).
154	Contact lens inserter/remover	Intended to insert and remove contact lenses from the eye.
155	Continuous glucose monitor retrospective data analysis software	Intended to analyze and correlate retrospective data from a continuous glucose monitoring device.
156	Controlled ankle motion (CAM) walker	Intended for preventing/limiting foot/ankle movement in cases of serious sprain, surgery or removal of cast
157	Core-body mechanical weight exerciser	Intended to enable a patient with a lumbar spine injury to perform controlled extension, contraction, and/or twisting movements of the lumbar/thoracic spine back region and the abdomen, for testing and rehabilitation.
158	Corn/callus dressing, reusable	The device is intended to offer symptomatic relief of physical foot disorders and similar conditions, by providing a mechanical barrier which relieves the effects of pressure and friction and or support.
159	Corn/callus dressing, single use	A non-sterile adhesive dressing intended for protection and/or relief of corns or calluses (hardened areas of skin on the feet or toes).
160	Cotton and rubber elastic bandage	It is and elasticated device intended to be worn on limbs for managements of sprains, strains and painful joints on intact skin.
161	Cotton crepe bandage	It is intended to be worn on limbs for managements of sprains, strains and painful joints on intact skin.
162	Cottonoid pad	A device that is placed next to the parotid gland in order to absorb the saliva that is being secreted. This aids in dental procedures as it helps maintain a working field dry.

S.No.	Device Name	Intended Use
163	Cover for thermomete probe	It acts as a physical barrier between the patient and an in-the-ear thermometer to prevent cross-contamination between patients.
164	Cover, dental	To cover and protect a dental handpiece during dental procedures and prevent cross-transmission of infection between patients.
165	CPAP/BPAP chin strap, reusable	A device in the form of a strap or band intended to be fastened around a patient's head (vertically from chin to crown) during positive airway pressure (PAP) therapy to control mouth air leaks by gently holding the mouth closed.
166	CPAP/BPAP chin strap,single use	A device in the form of a strap or band intended to be fastened around a patient's head (vertically from chin to crown) during positive airway pressure (PAP) therapy to control mouth air leaks by gently holding the mouth closed.
167	Cranial orthosis, pediatric	A patient-matched helmet-like device, intended to be worn on the head of an infant with an abnormal head shape (e.g. due to plagiocephaly, brachycephaly) to improve cranial symmetry/shape during growth over a period of months.
168	Crash cart/Emergency recovery trolley	Intended for use in hospitals for transportation and dispensing of emergency medication/ equipment at the site of a medical/surgical emergency for life support protocols.
169	Crutches	Intended to help transfer of load from the legs to the upper body of people who cannot use their legs to fully support the weight of their body due to temporary or permanent disabilities.
170	CT phantom, test object	Intended to establish, validate, and provide for routine and periodic verification of patient imaging CT system performance consistent with internationally recognized standard.
171	Custom-made anatomy model	A model of the bone of a specific patient intended for use to facilitate accurate preoperative planning and introperative placement of a device during orthopaedic surgical procedures.
172	Cytotoxic waste receptacle	Intended to safely deposit, collect and store cytotoxic materials (e.g., chemotherapy/antineoplastic drugs).
173	Dappen dish, reusable	Intended to hold and mix dental materials.
174	Dappen dish, single-use	Used to hold and knead dental materials.

S.No.	Device Name	Intended Use
175	Denis Brown splint	Intended to immobilize the foot, particularly on young children with tibial torsion (excessive rotation of the lower leg) or club foot.
176	Dental abrasive disk guard	A dental device intended to be fitted around an abrasive disk when rotating at high-speed to protect tissues not intended to come in contact with the abrasive disk.
177	Dental abrasive disk, reusable	Intended for use in contouring, finishing, and polishing dental restorations.
178	Dental abrasive disk, single-use	Intended for use in contouring, finishing, and polishing dental restorations.
179	Dental abrasive strip, reusable	It is intended to be used for cleanup, polish or finish dental crowns and bridges after cementation of crowns, veneers, bridges, inlays or onlays.
180	Dental abrasive strip, single-use	It is intended to be used for cleanup, polish or finish dental crowns and bridges after cementation of crowns, veneers, bridges, inlays or onlays.
181	Dental amalgam mixer	This is a dental benchtop amalgamator that is intended to mix by vibration/shaking, encapsulated materials to be used for dental restorative procedures in the mouth.
182	Dental articulation liquid	A range of pressure indicating material used to locate areas of denture or removable dental device discomfort in the patients mouth. Used for seating crowns, bridges, full dentures, immediate dentures and partial dentures.
183	Dental articulation paper	Intended for marking areas of contact between opposite teeth, restorations or appliances.
184	Dental automated x-ray film processor	A mains electricity (AC-powered) automated dental x-ray film processor designed to be used in the dental practice for the rapid processing of films.
185	Dental cheek retractor, home-use	This is a hands-free, self-retaining frame that is intended for home use by a patient to retract the lips/cheeks to facilitate viewing of the teeth.
186	Dental cotton roll	It is intended as an absorbent, hard-packed cylinder (a roll) that is used as a saliva absorber from the oral cavity during dental procedures. It may also be used as a packing between the lip/cheek and the gum to give better examination/operative exposure.
187	Dental cuspidor	This is a vessel, e.g. a round bow, into which the patient may expectorate during and after dental procedures.

S.No.	Device Name	Intended Use
188	Dental floss	It is a tape/thread-like device intended for removing plaque, food debris, etc. from between the teeth and aid in prevention of dental caries
189	Dental implant abutment analog	A rod-like device intended to be used as a copy of a dental abutment, for a dental laboratory working model, to confirm the orientation/position of the final dental abutment placement; it may be used during a scanning procedure
190	Dental implant abutment impression cap	A device intended to be placed intraorally on the abutment head of a dental implant during dental impression procedures, to facilitate the removal of the impression material after setting and to ensure the position of the implant in order to transfer it to a working model for the dental technician.
191	Dental implant/prosthesis handling forceps	This is a hand-held manual dental instrument designed for grasping and holding a dental devices(e.g., crown, bridge, screw) during its application to a patient's oral cavity
192	Dental impression adhesive	A liquid material specifically made to give adhesion of an impression material to the impression tray.
193	Dental impression material	Intended to take an oral impression.
194	Dental impression material kit, reusable	A collection of non-sterile devices designed to obtain a negative imprint of the teeth. The kit typically includes dental impression materials and a dental impression tray(s).
195	Dental impression material kit, single-use	A collection of non-sterile devices designed to obtain a negative imprint of the teeth. The kit typically includes dental impression materials and a dental impression tray(s).
196	Dental impression material mixer	An electric device used to mix impression materials immediately before use at the chair side
197	Dental impression tray material	A material intended to be used to create a custom impression tray intended for filling with dental impression materials; it is not intended for the fabrication of a patient-worn dental appliance.
198	Dental impression tray, reusable	A impression tray is a metal or plastic device intended to hold impression material, to make an impression of a patient's teeth to reproduce the structure of a patient's teeth.

S.No.	Device Name	Intended Use
199	Dental impression tray, single-use	A impression tray is a metal or plastic device intended to hold impression material, to make an impression of a patient's teeth to reproduce the structure of a patient's teeth.
200	Dental laboratory CAD/CAM unit	This is a laboratory based device that is intended to be used to aid in the computer-aided design (CAD) and manufacturing/production (CAM) of dental restorations in the dental laboratory.
201	Dental material application tool, reusable	Intended to be used in dentistry for the application of a dental material (e.g., composite resin, etchants, etc.) to a dental prosthesis or to a patient's tooth/teeth or elsewhere in the oral cavity
202	Dental material heater	Intended to heat regular (paste) and flowable composite material, including bulk fill composites, compules, porcelain veneers and onlays
203	Dental material mixing surface, reusable	Intended to be used as a surface to mix dental materials.
204	Dental material mixing surface, single-use	Intended to be used as a surface to knead or mix dental material (impression material, cement, etc).
205	Dental matrix wedge	Used to wedge between teeth to create space when applying restorative materials
206	Dental pick	Intended for the removal of plaque and/or debris from the proximal surfaces of teeth and the gingival surfaces of fixed prostheses.
207	Dental precision attachment fitting/adjustment tool	This is a hand held dental laboratory instrument that is intended to be used in a dental laboratory or dental surgery during fabrication or revision of a final dental prosthesis (e.g., denture, crown, bridge) to integrate and/or adjust the fitting between male and female precision attachments.
208	Dental resin applicator	Intended to be used for the application of a dental restorative material (e.g., amalgam, resin) to a patient's tooth/teeth; the restorative material is not included.
209	Dental rubber dam	Dental rubber dam is a stretchable sheet used to isolate a field of work from the rest of the oral cavity in dentistry.
210	Dental spatula, reusable	Used for kneading or mixing dental material (impression material, cement, etc).
211	Dental spatula, single- use	Used for kneading or mixing dental material (impression material, cement, etc).

S.No.	Device Name	Intended Use
212	Dental suction system fluid-separation unit	A separator used in the oral cavity for the separation of fluids (saliva, blood) from gases to avoid liquids from entering the suction pump (i.e., dry suction).
213	Dental surgical microscope	This is a dental device that is intended to be used to magnify and visualize minute intraoral structures during dental examination and dental surgical procedures in the mouth.
214	Dental torque wrench adaptor	It is used to enable connection of the main body of the wrench to a specific endpiece(s).
215	Dental X-ray beam aligner	Intended to assist the dental radiographer position the positioning indicator device relative to the tooth and receptor
216	Dental X-ray film holder	It is used to hold the dental xray films and position it to the right angle inside the mouth to aim taking an accurate xray
217	Dental/oral lavage unit (water flosser)	Intended to inject a stream of water on teeth to remove dental plaque in between teeth and improve gum health. It is intended as an OTC (home use) device.
218	Dental-professional prophylaxis brush/Dental polishing brush	A rotary dental instrument with natural or synthetic bristle brushes intended to be used by a dental hygienist and/or dentist to clean and polish teeth.
219	Dentifrice	Prophylaxis pastes without fluoride intended to be used by professionals for tooth cleaning and polishing procedure by abrasion/mechanical cleaning only.
220	Dentures cup	This cup is intended to hold patient dentures when they are not in the mouth.
221	Dermatome skin approximation tape	Intended for attachment onto a skin graft knife to collect a skin graft tissue.
222	Dermatoscope	Intended for non-invasive, visual inspection of intact skin by a healthcare professional.
223	Derotation bar with Traction	Intended for lower limb traction and aid in early healing, correction of drop foot
224	Diagnostic condensing lens	Intended for use in binocular indirect ophthalmoscopy to focus reflected light from the fundus of the eye.
225	Diagnostic X-ray system positioning frame	Diagnostic X-Ray System positioning frame
226	Diagnostic x-ray tube mount	Intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.

S.No.	Device Name	Intended Use
227	Dialysis bag clamp/clip	Intended to be used for opening or closing the dialysis tube.
228	Dialysis set holder	To hold and secure in position a dedicated set being used during a dialysis procedure.
229	Diaphragm wearable urinal	A non-sterile urine drainage device designed for men with incontinence consisting of a front piece with a scrotal support and a leak-proof, flexible diaphragm through which the penis passes into a closed coneshaped tube connected to a leg bag into which the urine is collected.
230	Digital examination camera	Digital camera for close-up skin inspections or general examinations.
231	Direct ophthalmoscope eye cup	The device is intended to be attached to the distal (patient-contact) end of a direct ophthalmoscope head to facilitate appropriate positioning around the patient’s eye socket during an examination.
232	Disability vehicle, moped	A moped that provides mobility to a disabled person
233	Disposable Kelly pad	Intended to funnel blood to a collection device in order to help detect postpartum hemorrhage
234	Dissection board	A device on which an object is placed for support during dissection procedures
235	Douche kit	A packaged collection of items (douche solution prefilled in a douche unit) used to provide cleansing of the vaginal area of the user's body.
236	Drainage tube	A hollow device used as a conduit to remove fluids or purulent material from a cavity, wound, or infected area.
237	Drape adhesive	Intended to be placed on the skin to attach a surgical drape.
238	Draping incontinence liner	A non-sterile padded sheet intended to cover a device/piece of furniture (e.g., wheelchair, bed, sofa) occupied by an incontinent person to catch and retain urine.
239	Dressing retention garments	Intended for use in wet and/or dry wrapping and dressing retention in the treatment of atopic eczema.
240	Drip wearable urinal	A non-sterile urine drainage device designed for men to contain a moderate leakage consisting of a front piece with an integrated tubular sheath that fits fully over the penis and into which dribbling urine is collected.
241	Dry powder inhaler	Intended to administer powdered medicine through the mouth and into the bronchial airways.

S.No.	Device Name	Intended Use
242	Dry salt therapy device	Intended to provide an inhalation of prefilled salt particles through the mouth and into the bronchial airways to induce natural self-cleansing mechanisms that flush away the impurities from the surface of cells and mechanically clean the airways.
243	Drying chamber for breathing circuits	A chamber designed for drying breathing circuit equipment.
244	Ear bowl	Intended to fit the curvature of the head and sit closely under the ear lobe to enable ear treatments.
245	Ear canal impression tray	Intended to hold and confine the impression material in opposition to the surfaces to be recorded, and to control the impression material while it sets to form the impression of the ear canal.
246	Ear canal light	Intended to illuminate the ear canal.
247	Ear Irrigation kit	Irrigates the ear canal with solution to clear wax and debris.
248	Ear microsystem needle	Intended to apply continuous pressure to stimulate meridian points during auriculotherapy
249	Ear wick	Intended to minimize bleeding during ear surgery.
250	Elastic adhesive Bandage	It is intended to secure dressings and for strapping on intact skin
251	Elasticated cohesive Bandage	It is intended to secure dressings and for strapping on intact skin
252	Elbow immobilizer	A non-rigid external device, usually made of a fabric, used to temporarily render the elbow immovable to support healing of an injury or a surgical wound.
253	Elbow orthosis	A prefabricated (non-customized) externally applied and wearable orthopaedic appliance designed to encompass the elbow joint to support, align, prevent, or correct deformities/injuries or to improve function of the elbow.
254	Electric dental chair without operative unit	A mains electricity (AC-powered) device designed to support a patient in a seated position to facilitate dental examination, treatment, and/or minor surgery procedures. It does not include operative unit.
255	Electric stander	Standing frames for those with standing difficulties
256	Electric toothbrush	Intended to remove plaque, tartar, food debris, etc. from teeth and gums and aid in prevention of dental caries, etc.

S.No.	Device Name	Intended Use
257	Electrical-only medical device connection adaptor	This device connects incompatible plugs/sockets on related medical devices (e.g., video control centers, peripheral devices and controller) and/or cables and relates the control signals.
258	Electronic occlusion spectacles	Intended to test and train vision for conditions where decreased visual acuity may be due to unequal vision in the eyes.
259	Electrosurgical electrode holder	A device intended to be used to house active hand-controlled electrosurgical electrodes (pencil electrodes) when not in use during the surgical procedure.
260	Emesis bag	A disposable device intended to collect and contain a patient's vomit and eliminate exposure to vomit until it is convenient to dispose of the bag and its contents.
261	Endaural wax extraction curette	This device is intended to simply extract ear wax using a soft silicone tip that expands in ear cavity to aid extraction.
262	Endoscope calibration cover, reusable	A plastic cap/cover designed to be placed onto the distal end of an endoscope to allow white balance and/or 3-D adjustment to be calibrated in the electronic control unit of the endoscope. This is a reusable device.
263	Endoscope channel cleaning valve	An adapter or valve to be fitted to an endoscope for cleaning purposes
264	Endoscope cleaning brush	A device used to remove dirt or debris from the working channel (s) and irregular surface of the endoscope prior to disinfection and sterilization.
265	Endoscope collector	A device intended to collect the excreted endoscopic video capsule camera.
266	Endoscope flushing adaptor, single-use	An adapter intended to be fitted to an endoscope air/water channel for flushing of the endoscope during post-procedural ‘precleaning’ step of endoscope reprocessing after endoscopic procedure.
267	Endoscope leak tester tubing	Leak tester tubing for use during endoscope leak test.
268	Endoscope/instrument holder, manual-adjusted	A manually adjusted device intended to be used to hold, maintain in a desired position, and enable positional adjustment of an endoscope (e.g., laparoscope) and/or associated instruments/devices during an endoscopic examination/surgical procedure.
269	Endoscopic irrigation/aspiration foot-pedal	A manual, foot-operated device intended to be used in conjunction with an irrigation tubing set to facilitate delivery of sterile irrigation fluid.

S.No.	Device Name	Intended Use
270	Endoscopic video image interpretive unit	The device is intended to be used by trained clinicians as an adjunct to video Endoscopy for the purpose to highlighting regions with visual characteristics consistent with different types of mucosal abnormalities.
271	Endoscopic video image processor	A unit designed to receive the electronic signals sent from a video endoscope and may/may not compensate for/enhance the colour and light qualities provided.
272	Endotracheal tube holder	Intended to provide a reliable stabilization of endotracheal tube after intubation
273	Endotracheal tube introducer	Intended to help with the insertion of an endotracheal (ET) tube into the airways of a patient during intubation
274	Enema bag	Intended to be used to hold an enema solution for administration into the rectum
275	ENT chair, electric	Intended to support a patient in a seated position, electrically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.
276	ENT chair, mechanical	Intended to support a patient in a seated position, mechanically control position in a way to facilitate ear, nose, throat examination, treatment, and/or minor surgery.
277	ENT surgical microscope	Intended to magnify minute structures (e.g., nerves, vessels) in the performance of ear, nose, and/or throat (ENT) surgery requiring high magnification and adjustable focusing.
278	ENT transilluminator	Intended to illuminate sinus tissue during an ear/nose/throat (ENT) procedure to render the tissue translucent for examination
279	Enteric stomal shield	A non-sterile cap intended to be placed over an enteric stoma to protect it from harmful external influences (e.g., knocks, friction).
280	Enuresis alarm	The device that activates a signal when a small quantity of urine is detected by a sensing mechanism to help a child with training the bladder.
281	Epileptic seizure alarm	Intended to alert or notify healthcare professional or next of kin when an epileptic patient (often pediatric) gets a seizure attack.
282	Euthyscope	Intended to project a bright light encompassing an arc of approximately 30 degrees on the fundus of the eye for the treatment of amblyopia.

S.No.	Device Name	Intended Use
283	Exothermic heat therapy pack	Intended to be applied to the body surface, sometimes with pressure, to provide heat therapy to reduce muscle spasms and cramps and/or for joint and muscle stiffness and pain.
284	External asembled lower limb prosthesis	Intended for use as an preassembled external artificial limb for the lower extremity.
285	External limb prosthesis socket liner	Intended for use as an interface that goes between a person's skin and his or her prosthetic to protect the wearer's skin while enhancing comfort and maintaining a more consistent fit.
286	External lower-limb prosthesis socket	A component of an external lower limb prosthesis designed to fit over a residual limb after amputation at any hip, knee, or ankle-foot level, and intended to function as the limb-prosthesis interface and to provide support, stabilization and suspension.
287	External nasal splint	Intended for external use for immobilization of parts of the nose.
288	External silicone breast prosthesis	Intended to restore normal contour and improve function for patients who have experienced partial or total loss of their breast to traumatic injury, disease or due to surgical removal of the nose (rhinectomy).
289	Extractor	Used to aid in the removal of foreign objects from superficial skin tissue.
290	Eye cup	Intended to fit around the eye socket and placed over the eye to allow washing of the affected eye.
291	Eye irrigation shield	Intended for use with an eye irrigation kit/system to direct irrigation solution to the surface of the eye and allow the solution to gently lavage the surface of the eye.
292	Eye pad, non sterile	Intended for use as a bandage over the eye for protection or absorption of secretions.
293	Eye patch, non-sterile	A device with a synthetic origin used to close/cover one or both eyes, for the purpose of protecting the eye after a procedure or as part of an ophthalmic therapeutic intervention.
294	Eye patch, non-sterile	Intended to provide temporary occlusion for the eye in the treatment of Amblyopia, diplopia or as a occluder for vision or field testing.
295	Eye spud	Intended to remove a foreign body/object embedded in or adhering to the surface of the eye globe.

S.No.	Device Name	Intended Use
296	Eyelid clamp	Intended to automatically grasp and hold the eyelid during an ophthalmic surgical intervention.
297	Eyelid weight, external	Intended to be applied to the outside of the upper eyelid to "lidload" the eyelid to restore upper eyelid muscle function.
298	Face shield	Intended to protect the wearer's entire face (or part of it) from hazards such as chemical splashes (in laboratories or in industry), or potentially infectious materials (in medical and laboratory environments).
299	Feeding nipple	Intended for use as a feeding nipple for infants with oral or facial abnormalities
300	Felt tangent screen	Intended for assessing the extent of the patient's peripheral visual field by mapping the visual response to a test object moved from the periphery towards the centre of the screen.
301	Female wearable urinal, reusable	A non-sterile, urine drainage device designed for women that typically consists of a flexible tube attached to a collector that is specially formed to securely fit around the female genitals to provide a route to channel urine, via a tube, into a collection bag.
302	Fiber cast bandage	Intended to be used as a medical dressing made of synthetic materials to support and protect bones that have been broken or joints that need stabilization.
303	Filter for dental suction equipment	Filter that ensures debris does not enter dental suction equipment
304	Filter for gas central supply system	Designed to remove particulates and volatile organic compounds (VOCs) from the gas flowing into incubators used in IVF procedures.
305	Finger and toe bandage	An elastic, tubular device intended to be worn over/around the limb (arm/leg) and/or finger of a patient affected by a skin condition/disorder (e.g., eczema, wound, fragile skin) to protect the skin typically after treatment with a medication (e.g., ointment, cream), and/or to support a dressing over a wound/injury.
306	Finger Cot/brace	Intended to support, align, prevent or correct deformities/injuries or to improve function of finger

S.No.	Device Name	Intended Use
307	Finger/hand exerciser	Intended primarily to strengthen the muscles of the fingers and hands through repetitive finger/hand motion against resistance from elasticity or density (post fracture/stress/weak forearm and grip strength).
308	Finger/thumb prosthesis	Intended as an artificial substitute for a missing finger or thumb
309	Flatus tube, single-use	A soft and pliable tube intended to be inserted through the anus to relieve colic in infants. It is a single-use device.
310	Flex bar	Intended to increase tendon strength and reduce elbow pain for those who suffer from tennis and golfer's elbow.
311	Flotation therapy bed, adult	A mains electricity (AC-powered) bed designed to minimize pressure points on a patient's body by providing contact with as much of the body surface as possible, typically through a mattress that contains a large volume of constantly moving media, e.g., water, air, or mud that lifts the patient to simulate a floating effect. It is used in cases of decubitus ulcers or where a patient has little remaining body fat and the displacement of body weight is vital for treatment and/or comfort.
312	Flotation therapy bed, neonatal	A fixed (non-adjustable) device designed with a mattress or cushions containing air, water, gel, or other appropriate material used for the continuous care of newborns, and sick and/or premature babies.
313	Fluid delivery mount, general-purpose	The device is designed to hold the fluid bags when gravity irrigation is needed for scope surgery.
314	Foot traction kit	It is used in relieving pain due to muscle spasm, maintaining the limb in a position of comfort and to restore and maintain the alignment of bone due to fracture or dislocation.
315	Footstool, conductive	A low stool for standing on to compensate for height differences. It is intended to be used in, e.g. examination rooms or operating theatres.
316	Forceps, dressing	A surgical instrument with scissor like handles used to grasp dressings, e.g. cotton swabs, towel, lints
317	Forceps, sterilizer transfer	Forceps with specially designed blades used to handle sterile instruments or implants.

S.No.	Device Name	Intended Use
318	Fornixscope	Intended to provide indirect access and viewing of the upper conjunctival fornix and inner surface of the eyelid as an alternative to eyelid eversion.
319	Fresnel lens	Intended to be applied to the back of spectacle lenses to focus light to a focal point to help manage various vision conditions.
320	Fresnel prism	Intended to be applied to spectacle lenses to give a prismatic effect typically to manage strabismus or other eye muscle dysfunction.
321	Fundus camera	It is intended to capture and document digital images of the posterior and anterior segments of the human eye.
322	Fundus camera, pediatric	Intended to capture digital color images of the retina of infants having less than 55 weeks of Post Menstrual Age (PMA), while there eyes are dilated using mydriatic drops under clinical control.
323	Gait rehabilitation electronic walker	A mobility and transfer device that helps a health care professional raise a patient to a standing position, providing support for standing or ambulation, or lifting a patient in the seated posture and transferring them between wheelchairs, chairs, toilets, beds or therapy tables.
324	Gait Trainer	It is used to assist and train a person with physical disabilities to relearn/improve walking.
325	Gait trainers-Unweighing System	Intended for partial weight-bearing therapy in rehabilitation
326	Gas sampling line filter, reusable	The device is indicated for adult, pediatric, infant/neonatal patients for removal of moisture from the gas sample.
327	Gastric pH strip	pH strips to indicate the pH level of human gastric aspirate
328	Gel base for metallic neuro head frame	It is used for providing support patient's head in a suitable and stable position (e.g., supine, lateral, or prone) during intracranial and spinal surgeries.
329	Gel knee ring	Intended to be worn around the knee for pain relief and immobilization

S.No.	Device Name	Intended Use
330	Gel-filled bed mattress	A large, durable, fabric case filled with various densities of foam that support a gel structure, designed to be placed on a bed mattress support platform to provide a comfortable surface on which an occupant can lie, rest, and sleep, and intended to distribute body weight over a large surface area typically to help relieve pressure points for comfort and improve blood circulation to prevent pressure sores.
331	Gel-filled bed mattress overlay	A gel-filled pad or thin mattress, usually full-body length, which is placed on top of a bed mattress to distribute an occupant's body weight over a large surface area, typically to relieve pressure points for comfort and to prevent pressure sores.
332	Gel-filled chair cushion	A gel-filled pad designed to be placed on the seat of a chair to distribute an occupant's body weight over the surface of the buttocks, typically to relieve pressure points for comfort and to prevent pressure sores.
333	General-gas low pressure tubing, reusable	Intended to enable nitrogen or instrument air to be delivered to the console from the wall in the hospital.
334	General-purpose diagnostic x-ray phantom, anthropomorphic	A device that consists of preserved human or animal tissue, or a two or three-dimensional (3-D) tissue-equivalent model designed to mimic the functional, physical, or a combination of these characteristics of a normal or diseased human organ or organ systems. It is a quality assurance (QA) device intended to permit both subjective and quantitative evaluation of the overall function of both conventional and digital general-purpose x-ray systems and associated image acquisition, display and analysis computer programs.
335	General-purpose diagnostic X-ray phantom, test object	Intended to provide for routine and periodic verification of the energy, hardness and intensity of an X-ray beam
336	General-purpose manually-operated operation table	A mobile, manually-operated hydraulic table designed to be adjusted to support a patient during many types of surgical interventions.
337	General-purpose diagnosis/treatment table	Intended for use in general diagnosis and procedures in examination room to aid patient examination.
338	Gingival barrier (non-medicated)	Intended for protection of gingival area during tooth bleaching process

S.No.	Device Name	Intended Use
339	Gonadal radiation protector	Intended to attenuate unnecessary radiation exposure in diagnostic, medical or dental procedures, and shield the gonad of the patient and the operator.
340	Gonio lens	Intended for viewing the anterior chamber angle and retina
341	Gravity enema set	Intended to deliver an injection of fluid (e.g., saline solution) into the rectum to facilitate evacuation of the large intestine.
342	Grip-enhancing exoskeleton	Intended to improve grip strength and hand function for people (from children to elderly people) with impaired hand function. The condition may be (but is not limited to) due to orthopaedic or neurological problems, from birth or acquired. The device mimics the user's grip movements and supports the users' natural grip.
343	Gynaecological bib	Intended to be worn by the patient during gynecological examinations and procedures.
344	Gynaecological operating table top	Intended to support a patient during gynaecological surgical procedures
345	Gynaecological operating table, electrohydraulic or electromechanical or hydraulic	Intended to support a patient during gynaecological surgical procedures
346	Gynaecological surgical microscope	Intended to improve visualization of anatomical structures via transmitted light during gynaecological surgery (e.g., on the fallopian tubes).
347	Gynaecological examination/treatment table	Intended to support a woman's body in the appropriate positions during gynaecological examinations.
348	Haidinger brush imager	Intended to produce an image which facilitates visual function evaluation, particularly the macular integrity.
349	Hallux valgus metatarsophalangeal orthosis	A prefabricated (non-customized) non-rigid, home-use device intended to be worn on the foot to help prevent and/or reduce hallux valgus deformity, thereby reducing walking pain and bunion formation.
350	Hand exerciser table	This modality exercise is meant for rehabilitation of the hands, fingers, and wrist disorders injuries & fractures.
351	Hand/finger splint	Intended to immobilize an injured hand to protect from injuries to the digits, metacarpals, and wrist during the healing process.

S.No.	Device Name	Intended Use
352	Hand-carried stretcher	Intended to carry patient as an assistance for injury or disability.
353	Handgrip cover for laryngoscope	Intended to be placed over the reusable laryngoscope device during intubation to create a barrier in order to reduce the cleaning time and turnaround time of the laryngoscope blade for reuse.
354	Handgrip cover for surgical light	Intended to provide physical barrier on a handgrip to prevent cross-contamination between the operating room surgical lights (non-sterile) and the operating room personnel.
355	Handgrip cover for vein illumination device	The cover is intended to isolate vein illumination devices and simplify cleaning after use.
356	Hand-held telescope	Intended to enlarge images for a visually impaired patient/person.
357	Hand-held urinal, female	Intended as a container/set to be directly urinated into by a female (typically bed-bound) patient for excretory purposes.
358	Hand-held urinal, male, reusable	Intended as a container to be directly urinated into by a male (typically bed-bound) patient for excretory purposes.
359	Head marking cap	A head covering designed as a cap intended to be worn on the head of a patient to allow a healthcare professional to mark specific reference points on the head during a procedure [e.g., transcranial magnetic stimulation (TMS)] as an alternative to marking the scalp directly or to avoid cutting the patient’s hair.
360	Head reflector	A head-worn device consisting of a circular concave mirror (reflector) attached to a headband designed to reflect light to a site of examination/minor intervention (e.g., the nose, throat, or body surface) on a patient.
361	Head Rest/Ring	Intended to position and protect a patient's head, face and neck during prolonged surgeries
362	Heal cushion/Spur pad/cup	Intended to worn on the heel to relieve heel pain, plantar fasciitis, foot pain, pain during walking, calcaneal spur, sprain and strain of the foot, ankle, feet and knee pain.
363	Heat-sealing device	Intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.

S.No.	Device Name	Intended Use
364	Heel stirrup	Intended to position and support the patient's foot, lower leg and upper leg in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, general and robotic surgery.
365	Hip pad positioning device	It is used to support the patient hip during prolonged surgeries.
366	Hip protector (Belt)	Intended to be worn by older adults or patients who have balance/vision problems, bone conditions, or at risk of falling to prevent hip injuries and fractures.
367	Hip shield	A mechanical guard worn over the hip to reduce risk of injury in the case of a fall
368	Horizontal non-powered traction system	Intended to be attached to a table for the application of constant horizontal traction forces to the cervical or lumbar vertebrae of patient by means of attached harnesses.
369	Hospital Backrest	Intended to support patients with spinal problems and pain management
370	Hruby fundus lens	Intended for use in the examination of the vitreous body and the fundus of the eye under slit lamp illumination and magnification.
371	Hydraulic/pneumatic external knee prosthesis	This device is intended for transfemoral amputees, is a prosthetic device designed to restore some function of an anatomical knee joint.
372	Hydrocollator pack	Intended to be applied to the body surface to provide heat therapy to reduce muscle spasms and cramps and/or for joint/muscle stiffness and pain
373	Hydrotherapy equipment/tank	Used for rehab treatment requiring resistance created by water to aid in injury recovery, improve blood circulation, and decrease inflammation, speeding recovery time
374	Hydrotherapy treadmill	Intended for use in partially immersed in water, e.g., in a hydrotherapy tank, to provide additional resistance to the treadmill walking exercise without increasing the impact and/or stress on the patient's joints.
375	Hypothermia-prevention cap	Intended to prevent heat loss from the patient's head during surgery and under anesthesia.
376	Ice bag	Intended to alleviate pain and/or promote healing in minor injuries of the body or for application around the neck or limbs.

S.No.	Device Name	Intended Use
377	Image display monitor mount	A dedicated mount onto which a visual display unit (VDU), e.g., a patient monitor, can be placed and secured so that it is safely mounted in a position suitable for viewing. manufactured for hospital use.
378	Incentive spirometer	Intended to be used in respiratory therapy to encourage and motivate deep-breathing manoeuvres, typically for the postsurgical treatment and prevention of atelectasis (lung collapse) and to help facilitate airway opening and clearing.
379	Incontinence device suspender	A device used by a person with a disability to secure a body-worn incontinence device [e.g., a nappy (diaper) or a pad] in a stable and safe position
380	Incontinence penis clamp, reusable	Intended to gently compress the penis, either the proximal shaft or the glans penis, to occlude the urethra and prevent involuntary urination/dribbling for men who are incontinent of the bladder.
381	Indirect binocular ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures.
382	Infant acoustic earmuffs	A device consisting of two ear-covering cups (one for each ear) intended to provide noise insulation for neonates/infants in a special care unit.
383	Infant cap	To be used with an infant nasal CPAP respiratory support breathing system to act as a stabilizing head strap.
384	Infant care table	Intended for use in nursing, e.g., washing or changing of nappies, of newborn babies.
385	Infant incubator warming hood	Intended to provide warmth to an incubator chamber by placement above the chamber.
386	Infant inguinal hernia truss	Intended to be worn over the groin to prevent protrusion of abdominal contents in an infant with an inguinal hernia.
387	Infant limb immobilizer, reusable	Intended to temporarily render parts of an infant's body immovable, e.g., the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions.
388	Infant limb immobilizer, single- use	Intended to temporarily render parts of an infant's body immovable, e.g., the arms and/or feet while the patient undergoes therapeutic or diagnostic interventions.

S.No.	Device Name	Intended Use
389	Infant oral pacifier	To be used to calm the premature infant for longer duration specifically during Nasal CPAP or when infant is intubated and on mechanical ventilation. For hospital use only.
390	Infant resuscitation table	It is a patient platform that can be used to facilitate neonatal transition at birth. It provides a stable platform for mother side resuscitation and stabilization practices.
391	Infant sleep positioner	Intended to modify the sleeping position/posture of infants to prevent deformational plagiocephaly, a flattening of the back of the skull from a consistent back-sleeping position.
392	Infant-hammock bed mattress	Intended to be placed in a cot/crib/bassinet/bed/incubator and to cradle a young infant during sleep/rest, and can used for phototherapy, transportation and burns patients. Intended to help reduce the risk of infant injuries/disorders such as suffocation, flat head (plagiocephaly), sudden infant death syndrome (SIDS), pressure sores, and hyperthermia.
393	Infant-hammock bed mattress overlay	Intended to be placed on a cot/crib/bed mattress and to cradle a young infant during sleep/rest to help reduce the risk of infant injuries/disorders such as suffocation, flat head (plagiocephaly), sudden infant death syndrome (SIDS), and hyperthermia.
394	Inflatable hot/cold therapy pack/manual pump	A non sterile assembly of devices that are intended to be applied with pressure to a body surface to provide cold or heat therapy to that surface and/or underlying tissue, e.g. the muscle. This device typically consists of a cold/heat therapy pack, air inflation sleeve and a manual air pump with connection tubing. It is reusable and intended in both the professional and home setting.
395	Inflatable limb splint	A sleeve placed around an arm or leg and inflated to immobilize the limb.
396	Inflatable patient transfer sliding mattress, single-use	An inflatable device designed to support a recumbent patient on a bed or table and assist in the physical movement of a patient for safer, easier transfer and positioning in Trendelenburg and Reverse Trendelenburg.
397	Infusion line clamp	A device intended for the clamping of medical tubes.

S.No.	Device Name	Intended Use
398	Infusion line securement clip, single-use	The device is intended to hold tubing to avoid kinking of the tube during infusion and patient moving.
399	Inguinal hernia belt (Adult)/surgical truss, reusable	A reusable device Intended to relieve discomfort and hernia pain caused by an inguinal or sports hernia
400	Inguinal hernia belt (Adult)/surgical truss, singe use	A single use device intended to relieve discomfort and hernia pain caused by an inguinal or sports hernia
401	Injection site desensitizer, tactile	A non-sterile, noninvasive reusable device intended to be used to manually apply tactile pressure stimuli to a skin-surface injection site, prior to/during injection, to reduce the pain/anxiety/stress associated with injecting.
402	In-line arterial blood sampling set	A collection of devices designed to obtain an in-line arterial blood specimen while maintaining a closed system.
403	In-line backflow valve	A general-purpose device used in medical tubing or pipelines to prevent the backflow of gases or liquids.
404	Instrument lubricant	Intended to be applied to a surgical instrument prior to sterilization for purposes of lubrication/maintenance (e.g., to prevent moving or mating parts from sticking together during use, inhibit corrosion, and to improve longevity of the instrument)
405	Integration Unit for Flat panel x-ray detector	A portable, electrically-powered device intended to enable a direct flat panel detector (not included) to be integrated as part of an analogue x-ray [i.e., screen-film, computerized radiography (plate)] system to convert the analogue x-ray system into a digital x-ray system (retrofit) using the same modality components.
406	Intestinal ostomy base plate	The base plate is intended to fix the ostomy bag and adhere to intact skin around the stoma.
407	Intestinal stoma shield/support belt, reusable	A non-sterile plate intended to be placed over an enteric stoma to protect it from harmful external influences (e.g., knocks, friction), to reduce the risk of stomal herniation, or to help maintain adhesion of the base plate to the skin.
408	Intraoperative chest positioner	A preformed reusable pad designed to be attached to an operating table for stabilizing a patient's chest to adequately position, support, and reduce pressure on the bony prominences of the body part during intraoperative procedures

S.No.	Device Name	Intended Use
409	Intravenous access monitoring system, line-disconnection	An alarm system that connects to a sensors around/on a venous puncture site dressing or catheter connection to detect blood or disconnection of the catheter.
410	Intravenous catheter holder, non-sterile	It is a skin adhesive device for the securement of urinary catheters and medical tubing as part of ongoing catheter care.
411	Intravenous hanger, wall-mounted	The device is intended to be used within the medical application to hold infusion bags within the approved load range.
412	Intubation teeth protector	A device designed to fit over the upper and lower sets of teeth to protect them from damage during endotracheal (ET) tube intubation procedures.
413	Inversion table	Intended to support the body of a patient and provide traction for the back muscles and spine by allowing the patient manually invert their entire body in a supine position (feet up and head down), thereby assist in alleviating back pain.
414	Irrigation kit	To irrigate the nasal passages of infants and young children.
415	Irrigation tip, surgical mist	A device that is designed to connect to an air/water syringe to blow a mixture of air and/or water into a patient's mouth during dental procedures.
416	Jaw exerciser	Hard gum is used to exercise jaw muscles for temporomandibular disorders, increased saliva production, helping to improve efficient food chewing and swallowing.
417	Kinesiology tape	used to support and relieve pain in muscles, joints, and/or ligaments. It reduces swelling, increases mobility and enhances recovery.
418	Kinetic bed	Intended to enable continuous change of the patient's lying position.
419	Knee cap/brace/wrap	Intended to limit the mobility of the knee to relieve pain in conditions of arthritic pain, ligament/muscle injury, surgical procedures, fractures, sprains, etc.
420	Knee ice wrap	Intended to relieve pain, swelling and inflammation in the knee due to ACL, arthritis, sports injuries, sprains, strains, muscle fatigue and surgery.
421	Knife handle	A device that is an interchangeable component of a scalpel and that functions as a handle designed to mount a compatible blade.

S.No.	Device Name	Intended Use
422	Knife sharpener	A device used to create or re-establish a thin, keen edge or fine point on an instrument used to cut, such as a knife
423	Laparoscope laser adaptor	Intended to connect the laparoscope to the laser or the laser arm for laparoscopic laser treatment.
424	Laparoscopic surgery handle	A manually operated handle of various configurations to hold instruments used in laparoscopic surgery.
425	Laparoscopic tray	Intended for holding laparoscopy instruments during a laparoscopic intervention or sterilization.
426	Laryngeal airway introducer	A device intended to aid insertion of a laryngeal airway into the pharyngeal cavity of a patient while reducing or eliminating the need for finger manipulation within the mouth.
427	Laser protection eyewear	Intended to be used by the staff in an operating or treatment room where a laser is being used, in order to protect their eyes from injury during the laser surgery.
428	LED transilluminator	Intended to provide optimal LED light in the incubator
429	Leg intraoperative repositioning support	A mechanical device intended to be used to help support the weight of a patient's leg when the leg needs to be repositioned during an orthopaedic procedure. It is designed to be attached to the operating table.
430	Lens system, high magnification	A device (lens) used to observe the retina or anterior chanber of the eye.
431	Lice comb	Removes head lice eggs and nits and can be used in conjunction with all lice treatments
432	Light beam patient position indicator	Intended to project a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam.
433	Limb/torso/head restraint, reusable	The devices are designed to position and support patients in a variety of surgical procedures including, but not limited to gynecology, urology, laparoscopy, general and robotic surgery during Reverse Trendelenburg positioning.
434	Liquid barrier dressing, dental	Protection of gingival area during tooth bleaching process
435	Liquid crystal vein locator	Intended to indicate the location of a vein by revealing variations in the surface temperature of the skin.

S.No.	Device Name	Intended Use
436	Lower limb exerciser	Intended to provide above and below knee amputees the ability to improve muscle and strengthen residual limbs
437	Lower limb sliding exerciser, non-powered	A non-powered device intended to encourage active movement of a patient's lower limb(s) by assisting flexion/extension at the knee for rehabilitation. This is a reusable device.
438	Lower-limb orthosis	The device is an externally-applied wearable appliance intended to support and correct deformities of the leg and/or feet. It may be one of numerous different designs and is typically made of synthetic and textile materials. This is a single-patient reusable device.
439	Lower-limb warming sock/stocking, single-use	Intended to prevent heat loss during surgery and under anaesthesia. The patient's lower extremity is placed in the legwarmer which is equipped the same way as socks.
440	Maddox trial lens	Intended as a device that change the size, shape, and colour of an image to dissociate the eyes in the evaluation of eye muscle dysfunction.
441	Magnetic field shielding material for cochlear implants	An accessory intended to be used on Cochlear implant recipients to prevent implant magnet dislodgement during MRI scans. The device is placed externally on the recipient's head by a healthcare professional prior to undergoing an MRI procedure.
442	Mammographic x-ray phantom, test object	A device that consists of a uniform density or a two or three-dimensional (3-D) pattern of objects, materials or openings of varying dimensions. It is a quality assurance (QA) device used in both subjective and quantitative evaluations of various calibration and performance characteristics of dedicated digital or conventional diagnostic x-ray mammography systems or general-purpose x-ray systems adaptable for mammography applications.
443	Mammographic x-ray system compression paddle	A mechanically, electronically or software-controlled component of a mammographic x-ray system used to flatten and stabilize the breast during mammography studies or mammography system-guided biopsy procedures.

S.No.	Device Name	Intended Use
444	Mandible-repositioning sleep-disordered breathing orthosis	A removable intraoral device designed to alleviate sleep-disordered breathing conditions (e.g., snoring, obstructive sleep apnoea) by repositioning and/or controlling the lower jaw (mandible), typically in a downward and forward position.
445	Manual adjustable hospital bed	Intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed.
446	Manual dental burnisher, reusable	Used to polish the surface and smooth the margins of restorations during dental procedures.
447	Manual dexterity assessment software	The software is intended to detect micrographia (smallness of writing), bradykinesia (slowness of movement) and tremor with the help of an off-the-shelf tablet and a digital pen. This is not intended for self-assessment.
448	Manual dexterity test	Dexterity devices intended to evaluate motor coordination, depth perception and eye-hand coordination.
449	Manual radionuclide applicator system	Intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy.
450	Manual stander	A manually-powered, mobile device designed to support and lift a disabled patient to an upright standing position to provide the health benefits associated with standing (e.g., improved breathing, circulation, and flexibility); it is not intended to facilitate gait.
451	Manual toothbrush	An instrument designed to be used by a patient to manually brush clean their teeth and gums (i.e., remove plaque, tartar, stains, etc) and/or aid in prevention of dental disorders such as caries.
452	Manual wheeled stretcher	Intended to transport patients in a horizontal position as an assistance to injury or disability.
453	Manual-aperture-control diagnostic x-ray system collimator, non-motorized	A standard, non-motorized, diagnostic x-ray beam-limiting device whose aperture size/length/shutter assembly must be manually adjusted in order to match the size of the x-ray beam to the size of the x-ray cassette in use. An x-ray collimator is used to limit the effects of scattered radiation on image quality and to provide patient protection by eliminating exposure to non-target body areas.

S.No.	Device Name	Intended Use
454	Marker, dental use	This device range helps mark plaque areas on a tooth and is thus intended to be used to aid disclose/make marks that allows identify dental plaque.
455	Mask strap	A head strap used to hold and stabilise a CPAP or BiPAP face mask onto a patient's face.
456	Massage table/couch	Intended for supporting body during therapeutic massages (not intended for general wellness purpose).
457	Maternity belt	It is used to support the belly bump during the different prenatal periods to avoid forward & downwards stomach pulling, provide maximum support and relieve back & pelvic ache.
458	Mechanical dental chair without operative unit	Intended to support a patient in a seated position to facilitate dental examination, treatment, and/or minor surgery procedures. It does not include operative unit.
459	Mechanical-resistance external ankle-foot external prosthesis	External prosthetic components for the purpose of replacement for a foot/ankle. The foot/ankle is intended to be used for a lower limb external prosthetic system
460	Mechanical-resistance external knee external prosthesis	An externally applied component for use in replacement of the knee joint (or other) in persons with limb amputation or difference.
461	Mechatronic external ankle-foot prosthesis	The device is intended as a part of an external prosthetic system that replaces the foot and ankle function of a missing lower limb.
462	Medical compression stockings	Intended for management/prophylaxis of leg pain, deep vein thrombosis, varicose veins and related complications
463	Medical equipment drape, single-use, non-sterile	A flexible polymer sleeve designed to form a protective water-resistant enclosure around a piece of medical equipment such as intra-oral cameras and its equipment components. It is intended as a hygienic barrier to protect the contents from soiling and contamination when used in the vicinity of, or entered into, a hygienic area. It is neither a dedicated handle cover, device cap nor an ultrasound transducer cover.
464	Medical examination light (AC powered or Battery)	Intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.

S.No.	Device Name	Intended Use
465	Medical gas terminal unit	A device that is a component of a medical gas pipeline system or a medical gas/vacuum pipeline system that has a gas-specific outlet connection for a single/mixture of gas to which the operator can connect and disconnect a medica device.
466	Medical image printer	A non-invasive, reusable printer that produces hard copies of medical video images.
467	Medical image storage device	Intended to provides electronic storage and retrieval functions for medical images.
468	Medical image storage device	A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.
469	Medical imaging recorder	A non-invasive, reusable electrically powered device designed to be used in conjunction with video endoscopes, and/or surgical video imaging devices to digitally record video images.
470	Medical instrument cable/lead	A reusable cable that functions as a conductor between power source and the medical instrument used for the purpose of transmitting an energy that may, or may not, contain information.
471	Medical print paper	Thermal paper to be used to produce hard copy of printed data generated by a medical device. For recording the EEG,ECG, EMG output from the ECT device.
472	Medical support stocking	Intended to be worn on the upper or lower extremity to support, correct, prevent deformity, or to align body structures for functional improvement.
473	Medical x-ray film, non-screen	A non-screen x-ray film specifically designed for use in medical imaging applications. Non-screen x-ray film is designed for direct exposure to x-rays and is relatively insensitive to the visible light emitted from screens.
474	Medical/cadaver body bags, non sterile	Intended for transporting a human corpse without any spread of biohazard/infectious agent.
475	Medical/Orthotic insoles	Intended to be worn inside shoes/footwear to relieve heel pain, plantar fasciitis, foot pain, pain during walking, calcaneal spur, sprain and strain of the foot, ankle, feet and knee pain.

S.No.	Device Name	Intended Use
476	Medicine chamber spacer	A device intended to be placed between a nebulizer or a metered dose inhaler (MDI) and the patient's mouth, to function as a reservoir into which an aerosol medication is dispensed in order to minimize delivery of large aerosolized particles.
477	Medicine cup	A specially designed cup used by the nursing staff when they are administrating tablets or pills to patients. It may be used both for tablets and fluids.
478	Meibomian gland camera	It is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands.
479	Meibomian gland expressor/evaluator, manual	A non-powered, hand-held manual ophthalmic instrument intended to be used to apply pressure to the lower eyelid to facilitate natural release and/or expression of meibomian gland secretions (meibum) to treat dry eye syndrome.
480	Metatarsal pad	Intended to relieve chronic metatarsal pain, corns, hard skin, morton’s neuroma, forefoot soreness, and painful balls of the feet.
481	Micropore tape	Intended for dressing retention on non-flexing areas and may also be used for patients who have exhibited an adverse reaction to adhesives based upon zinc oxide, rubber, or resin.
482	Microscope cover	This is a device which is usually shaped to fit the surgical camera/microscope that is intended to be used as a physical barrier to prevent cross-contamination between staff or patients during examination.
483	Mirror-prism spectacles	Intended to enable the patient to see over the top of their head enabling them to look forward in the direction their head is pointing.
484	Mobile radiation protection barrier	Intended to protect the operator etc. from unnecessary exposure to radiation used for medical diagnosis, treatment and dental procedures.
485	Moist-cold pressure bandage	A pressure bandage intended to provide a cool and to compress a local area of the body.
486	Moldable splint	A moldable splint device that is intended for use as an immobilization of non- or minimally displaced wrist fractures, contusions, and sprains

S.No.	Device Name	Intended Use
487	Motorized diagnostic imaging view box	Intended to retain, retrieve, and project light for direct observation of medical images taken using a variety of methods such as X-ray, magnetic resonance (MR), CT, and ultrasound, and recorded in radiographic film.
488	Mouth gag	To be used in dentistry to be placed between the teeth of a patient in order to maintain an open oral cavity during dental procedures.
489	MRI enhancement padding	Dielectric pads that are intended for use with magnetic resonance imaging systems to aid in body positioning and help reduce shading artifacts associated with the air/tissue interface during abdominal, pelvic, and neck imaging.
490	MRI examination catheter holder	The device is intended to be used with ICP catheter kits to enable the catheters to be left in during MRI scanning.
491	MRI phantom, test object	Intended for both subjective and quantitative evaluations of various calibration and performance characteristics of magnetic resonance imaging systems and associated image acquisition, display, and analysis computer programs.
492	MRI system chair	A chair or stool specifically designed to support and position a patient during examinations involving the use of a diagnostic magnetic resonance imaging (MRI) system. For MRI system compatibility these chairs/stools are made of ferromagnetically inactive materials.
493	Multi-chamber venous compression system garment, reprocessed	Deep Vein Thrombosis (DVT) Garments are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. When coupled with an appropriate inflation system, garments are intended for use in preventing deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency.
494	Multi-modality therapeutic radiation phantom, test object	This device is intended to establish and provide for routine and periodic verification with use of target motion of patient dose and machine output in therapeutic radiation oncology system performance.

S.No.	Device Name	Intended Use
495	Multiple spinal region orthosis	This is a body worn device that is intended to provide full circumferential containment when reduction in gross spinal motion about the lower thoracic and lumbar spine is required. This may include post operative spinal stabilisation, fracture and related soft tissue injuries
496	Nappy changing table, portable	Intended to support an infant, child or an adult during nappy (diaper) changing, or for a patient with a disability who is incontinent and requires regular changing of their nappies.
497	Nasal aspirator, electric	Intended for superficial use to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing.
498	Nasal aspirator, manual	A portable, hand-held, manual suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing.
499	Nasal dilator	Intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow.
500	Nasal Irrigation kit	To cleanse or flush the nasal passages and sinus cavity with saline for postoperative, preventive, or symptomatic nasal care.
501	Nasal scissors	A surgical instrument used to cut tissue during surgery on the nose and its associated structures. It comprises two pivoted blades usually provided with finger and thumb holes. The distal end of the blades may be different shapes.
502	Nasal septum straightening forceps	Intended to straighten the nasal septum through grasping and manipulation of the bone/cartilage of the septum during nasal reconstructive procedures.
503	Nasogastric tube holder	This device is intended to secure nasogastric tubes to skin near and around the nose.
504	Nasogastric tube holder, intranasal	The device is used with enteral feeding tubes to prevent inadvertent removal or displacement of the tubes for adult patients.
505	Nebulizer tubing set	A device intended to be connected to a nebulizer and transfer medication from the nebulizer to the patient with respiratory disorders.

S.No.	Device Name	Intended Use
506	Needle guard	Intended to encapsulate needles withrawn from vein or fistula thereby aiding in the prevention of needle stick injuries.
507	Needle holder	Intended to secure needles during suturing.
508	Needle holder, ophthalmology	It is intended to hold needle for procedure during eye surgeries.
509	Neonatal eye pad	Used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.
510	Neurosurgical chair	Intended to support and position a patient in a sitting or reclined position during neurosurgery.
511	Neurosurgical headrests	Intended to support the patient's head during a surgical procedure
512	Newborn-infant bed	Intended as support surface to newborn babies.
513	Nipple shield	Intended to aid infants with trouble latching onto the breast by acting like a longer, firmer nipple
514	Non-powered accelerator system table	Intended to adjust the patient's posture and immobilize the patient for radiotherapy.
515	Nonpowered flotation therapy mattress	Intended for medical purposes which contains air, fluid, or other materials, to treat or prevent decubitus ulcers (bed sores).
516	Non-powered neutron therapy table	Intended to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays.
517	Non-powered remote irradiation therapy table	Intended to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus.
518	Non-powered X-rays radiation therapy table	Intended to adjust the patient's posture and immobilize the patient for treatment using X-ray radiation therapy
519	Non-rebreathing oxygen face mask	A flexible, form-shaped device designed with valve to control rebreathing and contamination of gas, placed over the nose and mouth to deliver air of high oxygen (O2) concentration to a patient's airway for oxygen therapy.
520	Nose clip	It is a device used to help prevent air movement through the nose. It is typically used during pulmonary function tests to ensure that airflow is focused through the mouthpiece for accurate measurement.

S.No.	Device Name	Intended Use
521	Nuclear scanning bed	A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.
522	Nuclear sealed calibration source	A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.
523	Nystagmus inducing optokinetic drum	Intended to elicit nystagmus.
524	Nystagmus inducing tape	Intended to be moved across a patient's field of vision to elicit optokinetic nystagmus and to test for blindness.
525	One-piece urostomy bag	The ostomy bag is intended to collect output from a stoma. The adhesive is intended to fix the bag and adhere to intact skin around the stoma.
526	One-piece urostomy bag, open-ended	The product is intended for the management of stomal output.
527	Operating room shoes cover, non-sterile	Intended to be worn by operating room personnel during surgical procedures to protect foot of both the surgical patient & the operating room personnel from transfer of micro-organisms, body fluids, and particulate material.
528	Operating table traction frame	Designed to position, support and/or distract the patient’s hand, wrist, forearm and arm in a variety of surgical procedures including, but not limited to arthroscopic or Orthopedic surgery.
529	Operation theatre pendant	Intended to provide ergonomic solution for the positioning and management of medical devices, equipment, and utilities during surgeries and other medical interventions
530	Operator radiation protection spectacles	Intended to protect the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.
531	Ophthalmic equipment stand	It is used to keep the ophthalmic equipment like Slit Lamp, Keratometer, Laser etc.
532	Ophthalmic head reflector	Intended to reflect light onto the eye of a patient to allow examination of the eye and its associated structures.
533	Ophthalmic implant handling forceps, reusable	A reusable instrument used to grasp and manipulate ophthalmic implants (excluding sutures) during a surgical procedure.
534	Ophthalmic operating table top	Intended to provide support for and stabilization of the head of the patient and to help provide optimal access for the surgeon(s) during the intervention.

S.No.	Device Name	Intended Use
535	Ophthalmic surgery fluid collection bag	A fluid collection bag connected to a surgical system, used to catch aspirated material during an ophthalmic surgical procedure.
536	Ophthalmic surgical device handling forceps	Intended to grasp and manipulate a nonimplantable invasive ophthalmic surgical device (e.g., ophthalmic cannula, handless iris retractor)
537	Ophthalmoleukoscope	Intended for testing colour perception by means of colours produced by polarized light.
538	Opthalmic examintaion station	A device assembly intended to provide complete ophthalmic examination position and support conditions for the patient and clinician
539	Oral care swab	A foam headed oral swab impregnated with a sodium bicarbonate cleaning solution designed to be used wet to clean the teeth and oral cavity.
540	Oral exerciser	A device that is used to exercise tongue muscles as part of oral myology physiotherapy
541	Oral medicine dropper	Intended for aspirating a small volume of liquid medicine so that it can be dispensed in single drops into a patient's mouth, typically an infant or small child. It is a non-measuring device (non-graduated).
542	Orbital depressor	Intended to displace tissue to facilitate examination of the surrounding area in the orbital cavity during eye surgery.
543	Orthodontic aligner/retainer seater, reusable	A small cylindrical device intended to aid in positioning and seating an orthodontic progressive aligner or teeth retainer into place. This is a reusable device intended for single-patient use.
544	Orthodontic band pusher	A hand-held dental instrument designed for positioning and adapting metal bands on teeth in orthodontics.
545	Orthodontic positioner support kit	A collection of devices intended to be used to facilitate use of an orthodontic teeth positioner, including placement, removal and cleaning. It typically consists of an orthodontic appliance remover, an orthodontic positioner seater, and an orthodontic appliance cleanser. The positioner is not included. This is a single-patient device.

S.No.	Device Name	Intended Use
546	Orthodontic resin positioning tray	A custom-made dental device in the form of a patient's dentition which contains cavities intended to hold and facilitate positioning of light-cured dental resin onto teeth for subsequent attachment of an orthodontic appliance (e.g. aligner) after curing.
547	Orthodontic spring	The intended purpose of the orthodontic spring is to open and close space between teeth.
548	Orthodontic vibrator	Orthodontic predictability enhancement device designed to maximise the accuracy of fit and effectiveness of clear aligner treatment.
549	Orthopaedic bed	Intended to provide support for skeletal traction to stabilize fracture sites.
550	Orthopaedic bone pin holder	A non-sterile stainless steel cylindrical device intended to temporarily hold one or more orthopaedic pins (e.g K-Wires) during sterilisation & surgical procedure against damage.
551	Orthopaedic countersink	used for bone preparation to enable the placement of gingival part of components during dental procedures in the mouth.
552	Orthopaedic instrument extractor	A reusable surgical instrument designed to extract another orthopaedic instrument during an orthopaedic surgical procedure.
553	Orthopedic cast padding	It is intended to protect long prominences under the plaster on intact skin .
554	Orthopedic walker shoes/boots/Air cast boots	Intended for the treatment and rehabilitation of foot and ankle injuries and to provide support, stability, and protection to the foot and ankle during the healing process in cases of fractures, sprains, post-surgery, or severe foot or ankle injuries.
555	Ostomy adhesive	Adhesive to be placed around stoma to attach 2 piece ostomy collection device.
556	Otoscope cover	A disposable ear specula is a plastic cover which fits onto an otoscope to form a physical barrier protecting patients against cross contamination.
557	Otoscope, direct	Intended for examination of the outer ear canal and tympanic membrane (eardrum) by direct viewing through the ear opening.
558	Otoscope, endoscopic	Intended to be used in otology mainly for observation, diagnosis, and treatment of the outer and/or middle ear.
559	Oxygen administration hood	Intended to provide an enriched oxygen (O2) environment to increase the patient's O2 uptake.

S.No.	Device Name	Intended Use
560	Oxygen administration hood, paediatric	Intended to be used as an enclosure over an infant's whole body, or the head only, in order to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake.
561	Oxygen administration tent, neonatal/paediatric	Intended to cover the bed of a neonatal or small child to provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake. It is used for the treatment of breathing disorders in infant and paediatric patients permitting them movement without restriction.
562	Oxygen mask respiration indicator	Designed to be attached to the exhalation vent hole on the exterior of a standard oxygen face mask and provide visual indication of patient respiration.
563	Pacemaker test magnet	Intended to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.
564	Packer, gauze	To be used in dentistry and dental surgery for introducing and packing gauze or dressings into cavities.
565	Paediatric dorsiflexion slant board	It is intended to be used in the treatment of various medical conditions (e.g., congenital, neurological, post-traumatic) where tendon tightness and muscle contracture affect the ability to dorsiflex the foot, possibly leading to an abnormal gait.
566	Panniculus skin-adhesive retractor, reusable	This retractor is intended to be used on intact skin for positioning redundant tissue (i.e., post c-section, post laparotomy) away from the lower abdominal incision/wound.
567	Parallel bar exerciser	Intended to assist users in maintaining good walking posture, particularly a person with a disability, a paraplegic, or a patient who has suffered a stroke and is learning to walk.
568	Parapodium walking frame	Intended to encompasse and provide support for the body of a patient who is unable to stand unassisted to help them move (walk) by changing their centre of gravity (COG).
569	Partial hand radiation protector	Intended to protect part of hands and fingers from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.
570	Patient audiovisual communication system	It is intended for use by trained personnel in functional, interventional and clinical MRI environments to facilitate audio communications during a scanning session.

S.No.	Device Name	Intended Use
571	Patient enclosure system	A freestanding, framed, tent-like structure designed to be constructed on-site to function as a temporary enclosure for safe playing, resting or sleeping, typically for a patient with autism, epilepsy, challenging behaviours and/or learning difficulties. It has a soft fabric/plastic interior with padded regions to prevent injury, and a limiting and low-stimulation environment.
572	Patient gown, non-sterile	Intended to be worn by patients in a clinical setting (e.g., during hospitalization, during examination in a doctor's office).
573	Patient holder	The device is used to support patient's trunk and or lower limbs into a more symmetrical position. The intended patient group are those with disabilities who require assistance to maintain an optimal position, therefore preventing secondary complications such as joint contractures, pressure areas and pain.
574	Patient isolation tent canopy	A non-sterile covering designed to be used with a frame to provide environmental isolation of a contagious patient to protect hospital personnel and other patients from exposure to non-airborne infections (e.g. diphtheria, meningococcus) whilst the patient is being treated.
575	Patient lift	Intended as an assistive device to lift and transfer a patient with limited mobility from one place to another.
576	Patient transfer board	Intended to reduce the friction and difficulty during the task of moving or transferring a patient from a surface to another e.g. Bed to stretcher and reduce risks associated with manual handling by the staff
577	Pedal exerciser	Intended for exercise therapy for upper and/or lower body.
578	Pediatric gait trainers	Intended to assist and train children unable to walk or stand independently to enhance movement and independent ambulation
579	Pelvic floor exercise biofeedback device	It is intended for encouraging regular pelvic floor exercises; strengthening of the pelvic floor muscles; rehabilitation and training of weak pelvic floor muscle; treatment of stress, urge and mixed urinary incontinence in women; improving sexual pleasure or function in women with existing pelvic floor dysfunction; improving pelvic floor function in the post-partum period; improving mild to moderate prolapse symptoms

S.No.	Device Name	Intended Use
580	Pelvic traction kit (with/without weights)	Intended to apply uniform and controlled traction to the lumbar, sacral, and thoracic areas of the vertebral column.
581	Pen torch	Intended to assist with examinations by illuminating regions of the eye mount or ear.
582	Percussion hammer, manual	Intended to be used by an examining physician to gently tap near a patient's joints to test reflexes.
583	Periodontic hoe	A hand-held manual dental instrument with a small blade at an acute angle (e.g., 90 degrees) to its stem intended to be used with a pulling action to remove gross amounts of supragingival calculus, and some subgingival calculus, in large wide-open pockets where the gingival tissue is soft and easily cleaned.
584	Philadelphia collar (cervical)	Intended to be used in cervical fracture to support neck bones and ligaments by restricting the movement of the neck muscles
585	Phoropter arm	Used to mount the phoroptor during an ophthalmic examination; typically to mount the phoroptor to determine a patient's prescription for glasses.
586	Phototherapy eye protector, reusable	Intended to cover and protect the eyes of a patient or user from potentially harmful rays [e.g., ultraviolet (UV)] to which parts, or all, of their body is intentionally exposed during light therapy treatment.
587	Phototherapy eye protector, single-use	Intended to cover and protect the eyes of a patient from potentially harmful rays [e.g., ultraviolet (UV)] to which their body is intentionally exposed during light therapy treatment.
588	Phototherapy infant blanket	A piece of fabric, made from ultraviolet (UV) light transmittable material, intended to be used to wrap a newborn/infant during UV phototherapy for the treatment of neonatal jaundice (neonatal hyperbilirubinemia) to enable therapeutic light to pass through to the patient while simultaneously providing comfort. It does not include a light source.
589	Physical restraint	Intended to secure patient to chair, wheelchair, bed etc. to prevent self-harm or injuries to the health care professional handling the patient

S.No.	Device Name	Intended Use
590	Physical therapy table, line powered	Intended to facilitate functional training of patients/subjects with loss of lower extremity, upper extremity or core functionality, caused by conditions of orthopedic, musculoskeletal, neurological, or other origin by providing muscular load in combination with visual feedback.
591	Physio Motion Therapy BTL-CP Motion	Intended to be used during the first phase of rehabilitation following lower limb joint surgeries or traumas.
592	Picture archiving and communication system	A device intended for the recording, viewing, presentation and storage of digital still frames and video sequences for use with a microsurgical operating system.
593	Pill crusher/splitter	A hand-held device used for crushing or splitting medication in the form of a tablet for easier ingestion by a patient who cannot swallow the tablet whole.
594	Pinwheel	Intended for testing pain sensation
595	Plaster instruments/plaster saw	A instrument used to cut or shave or put plaster.
596	Plaster of Paris bandage	It is intended for support of fractured body part.
597	Plaster spreader	used to separate and spread hardened plaster
598	Pleoptophor	Intended for use during the treatment of eccentric eye fixation (casts in the eye) by dazzling the perimacular retina, thereby relatively enhancing the visual capabilities of the fovea.
599	Pneumatic external knee joint	Intended to replace knee joint in persons with lower limb amputation and connecting to above knee prosthesis
600	Pneumatic stander	Standing aid chair for Disabled Person
601	Pneumatic tourniquet and its attachment	Used for stopping flow of blood through artery by compression.
602	Pneumatic walker	To provide pneumatic compression and support to the ankle joint.
603	Polatest	Intended for evaluating hidden (latent) squinting, i.e., when the patient is not aware of the condition, and also when it cannot be seen.
604	Portable system mount	Intended to be fixed vertically within a clinical setting to enable the easy and secure mounting of a portable medical device.

S.No.	Device Name	Intended Use
605	Positioning aid system	A mattress system specifically designed for the disabled person allowing various positions to be maintained with the aid of positioning aids. designed to allow air flow to reduce sweating/heat and therefore the possibility of spasm.
606	Positron camera	A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body.
607	Postpartum maternity belt	It is intended to help reduce swelling, provide support to the lower back and abdominal muscles, and promote healing after delivery.
608	Postsurgical head/neck garment	It is a wearable contoured cranial cover intended for the restoration or augmentation of cosmetic appearance in patients with bony defects of the cranium.
609	Postsurgical transparent eye shield, vented	A device designed to be worn over the eye to protect the eye while allowing the wearer to see, typically following ophthalmic surgery. It is designed as a transparent self-adhesive dome which includes vent holes to allow air to circulate around the eye. This is a single-use device.
610	Power wheelchair	Intended to aid in mobility of individuals with physical disability, lack of senses in lower extremities and having difficulty in walking.
611	Power-assisted foot/hand-propelled tricycle	Power assisted foot/hand propelled tricycle designed specifically for people with disabilities
612	Prescription spectacles	An ophthalmic device consisting of a spectacle frame with a pair of optical spectacle lenses (typically made of plastic or glass, also known as eyeglasses) designed to be worn in front of the user's eyes to provide refractive corrections to eyesight conditions such as presbyopia (the eye's diminished power of accommodation that occurs with ageing), or refractive ametropia (myopia, hyperopia and astigmatism). The lenses may be tinted (sunglasses) to protect the eyes from bright light and radiation.
613	Professional examination gown, non-sterile	Intended to be worn by healthcare providers, sometimes over scrub suits, while examining patients to protect both the patient and staff from the transfer of contaminants such as microorganisms or body fluids.

S.No.	Device Name	Intended Use
614	Prophylaxis cup/ Dental polishing cup	This is a device that is intended to be used as a polishing cup to apply polishing agents during dental prophylaxis (cleaning). The device is held in a dental handpiece.
615	Proprioceptive nest	Intended to give physical support to the preterm newborn. It is designed to provide preterm babies with age-appropriate proprioceptive stimulation as well as comfort, a sense of security, and tactile stimulation.
616	Prosthetic external arm	Intended to be used as an external prosthesis for upper limb distal to shoulder joint by patients with upper limb loss or deficiency.
617	Prosthetic external foot (Winged Foot)	Intended for persons with a lower-limb amputation to restore lost mobility
618	Prosthetic foot, pediatric	Intended for children with a lower-limb amputation to restore lost mobility
619	Protective garment for Incontinence	Intended to protect an incontinent patient's garment from the patient's excreta.
620	Psychophysiological biofeedback system	Intended to improve certain medical conditions through user interaction, including anxiety, depression, pain, loneliness, mood and/or motivation; and for symptoms such as agitation, aggression, walking about found in some mental health disorders and/or neurocognitive disorders such as dementia.
621	Pulmonary equipment filter	Intended to prevent biological contaminants from entering pulmonary function testing equipment to help protect the patient and equipment during lung function tests.
622	Pulmonary exerciser	The device is a handheld device that is intended to improve expiratory/exhalation and inspiratory/inhalation muscle strength for the enhancement of breathing, coughing, swallow, voice and fitness.
623	Pupillograph	Intended for recording the response of the pupil to reflected light for ophthalmic diagnostic purposes.
624	Radiation face protector	Intended to protect the face and eyes of medical personnel and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment.
625	Radiation protection apron	Intended to protect the patient, the operator, and other personnel from radiation exposure during a medical or dental procedure.

S.No.	Device Name	Intended Use
626	Radiation protection blanket	Intended to protect specific body parts of the patient, operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.
627	Radiation protection cap	Intended to protect the head of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical procedures for diagnosis and treatment.
628	Radiation protection collar	Intended to protect the neck or thyroid of the patient, the operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment.
629	Radiation protection gloves	Intended for complete protection of the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.
630	Radiation protection goggles	Intended to protect the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment.
631	Radiation protection mitten	Intended to protect the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures.
632	Radiographic ECG/respirator synchronizer/X-ray synchronizer	A radiographic ECG/respirator synchronizer/X-ray synchronizer is a device intended to be used to coordinate an x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.
633	Radiographic film illuminator/X-ray LED view panel	A radiographic film illuminator is a device containing a visible light source (e.g., LED) covered with a translucent front that is intended to be used to view medical radiographs.
634	Radiographic film marking system/radiographic film marker	A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.

S.No.	Device Name	Intended Use
635	Radiographic film processor, automatic	It transports dental x-ray film from one solution to the next in the film developing process without any manual labour except the insertion of the film/cassette.
636	Radiographic film, non-screen	Intended to record images during diagnostic radiologic procedures.
637	Radiographic grid/X-ray grid/Anti-scatter grid	A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor
638	Radiographic head holder	Intended to position the patient's head during a radiographic procedure.
639	Radiographic intensifying screen	It is used to reduce the X-ray dose to the patient and to allow for shorter exposure times to reduce motion artefact on exposed film.
640	Radiographic/X-ray cassette holder (wall-mounted/ceiling mounted/floor standing)	Intended to be used as a support to hold and position radiographic cassettes for a radiographic exposure for medical use.
641	Radiologic patient cradle	Intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.
642	Radiologic table	Intended for medical purposes to support a patient during radiologic procedures.
643	Radiological breast positioning device, wearable	The device is indicated to aid in supporting adolescent and adult patients undergoing radiation therapy including electron, photon, and proton treatments. The device is also used during image acquisition to support treatment planning.
644	Radionuclide test pattern phantom	A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque material sealed in a solid pattern intended to serve as a test for a performance characteristic of a imaging device.
645	Rebreathing oxygen face mask	Intended to be placed over the nose and mouth to deliver a proportional mixture of air/oxygen (O2) to a patient's airway.
646	Reciprocating walking frame	Intended to be used a walking aid by people with physical disabilities or poor balance
647	Reclining wheelchair	A walking aid that reclines enabling the person to change positions from sitting to lying down.

S.No.	Device Name	Intended Use
648	Recording paper	This device is specially produced paper intended to be used for recording the output of devices measuring physiologic parameters, e.g. electrocardiogram (ECG), electroencephalogram (EEG) or ultrasound imaging or for recording fetal images.
649	Rectal dilator	Intended to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function. This is a single-patient use device and is intended for transient use.
650	Rectoscope/proctoscope handle	Intended to be used as a handle to hold a rectoscope or proctoscope during an examination procedure.
651	Rectosocope/proctoscope handle end-cap	Intended to be fitted to the proximal end of the handle of a rectoscope or proctoscope during an examination procedure to provide an airtight seal so that air can be pumped through the scope to inflate the bowel.
652	Rescue blanket	Intended to keep a person warm and/or to prevent the further loss of body heat in emergency/rescue situations.
653	Retractor holder	Intended for mounting of surgical retractors.
654	Reverse-image mirror, dental	A device designed to be placed at the back of the teeth while taking image for dental examination purposes.
655	Rib belt	Intended for providing support and compression to the ribcage and relief from rib pain and discomfort, especially after injuries or surgeries, supporting breathing and coughing during recovery, and preventing rib injuries in certain sports or physically demanding professions.
656	Rod cutter/reducer	Intended to be used to reduce or seat an implantable rod into the saddle of the implant.
657	Rollator	Intended as a walking aid for balance and stability in individuals with limited mobility.
658	Rongeur, dental	To be used in dental surgery to remove hard or tough body tissues such as cartilage or bone, by applying a biting/cutting action. This is a reusable device.
659	Rotating vestibular chair	A tilting and rotating chair intended to be used in clinical procedures for testing vestibular-ocular disorders.
660	Scalpel blade remover, non sterile	Intended to assist the removal of used/blunt blades from a scalpel handle during a surgical procedure

S.No.	Device Name	Intended Use
661	Scintillation (gamma) camera	A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector.
662	Scoop stretcher	Intended to transfer a trauma patient and reduce the chance of undesirable movement of injured areas.
663	Shaped ankle wedge prosthesis, adult	Intended to be used as external artificial joint that is designed to replace the ankle joint in adults
664	Shaped ankle wedge prosthesis, pediatric	Intended to be used as external artificial joint that is designed to replace the ankle joint in children
665	Shield, resuscitation	To minimise tissue contact and exchange of fluids between parties during mouth to mouth resuscitation.
666	Shoulder immobilizer	Intended to temporarily immobilize or limit abduction of the shoulder joint to support healing of an injury or a surgical wound.
667	Shoulder wheel	It is a device that allows patients to perform resistance exercises to improve range of motion and relieve pain (intended for hospital use)
668	Silicone prosthetic ear	Intended to adhere to the skin as an artificial external ear using safe, biocompatible glue for patients born with microtia and other birth differences such as Treacher Collins or Goldenhar syndrome; as well as those who have suffered traumatic injury or undergone cancer resection surgery.
669	Silicone prosthetic nose	Intended to restore normal contour and improve function for patients who have experienced partial or total loss of their nose to traumatic injury, disease or due to surgical removal of the nose (rhinectomy).
670	Single use binocular indirect lenses	Intended for visualization of the human retina (fundus) using a binocular indirect ophthalmoscope.
671	Single-chamber venous compression system garment, reprocessed	Deep Vein Thrombosis (DVT) Garments are part of an external compression system, in which intermittent compression is provided using a pump/controller and limb garment. When coupled with an appropriate inflation system, garments are intended for use in preventing deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency.

S.No.	Device Name	Intended Use
672	Sitz bath	Intended for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.
673	Sitz bath chair	Intended to support a person in sitting position for external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.
674	Skin abrasion device/file	Intended for debridement of thickened nails and callus.
675	Skin adhesive protective material	Intended to protect healthy skin from friction during removal of tapes and films. It provides a thin protective layer on the skin and helps tape and film adhesion.
676	Skin marker guide	A non-sterile device intended to be used as a guide to create markings on the skin surface with a drawing skin marker, typically to outline a surgical incision site or for dermatology applications. It is typically shaped specifically for its intended application.
677	Skin marking transfer paper	A non-sterile, non-invasive device intended to transfer a grid of ink dots onto the skin surface to assist a clinical procedure. This is a single-use device.
678	Skin pressure protectors	Intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores)
679	Skin-cover sealant/Synthetic polymer liquid barrier cream	This is a non-cytotoxic cyanoacrylate based liquid skin barrier film for the skin to form a transparent flexible film to prevent skin irritation caused by moisture eg. urine, friction from bedding and by adhesive products.
680	Slit Lamp	Intended to be used as a specialized magnifying microscope to examine the structures of the eye (including the cornea, iris, vitreous, and retina).
681	Snoring sensor	Intended for use in the detection of snoring, muscle movement, respiratory effort and/or airflow.
682	Soft dental reliner	Intended to be used as a tissue conditioner and a reliner for short term use for removable dentures. It may be intended for professional and/or home use.
683	Soft rehabilitation glove	Intended for rehabilitation training of patients with finger joint dysfunction.

S.No.	Device Name	Intended Use
684	Solid-ankle-cushion-heel (SACH) foot	Intended for persons with a lower-limb amputation to restore lost mobility
685	Spatula	An instrument, usually made of stainless steel, which is used to spread a material on a surface, to fill material into a cavity, manipulate tissue or to remove a material from a surface. This is a reusable device.
686	Spine orthosis	An externally-applied wearable appliance intended to support and correct deformities of the spine. It may be one of numerous different designs and is typically made of synthetic and textile materials. This is a single-patient reusable device.
687	Stair chair	Supports and transports a patient occupant in a seated position up or down a set of stairs.
688	Standing wheelchair	Intended as a walking aid that allows users to raise themselves in upright position using upper limbs
689	Steam inhaler	Intended for the inhalation of steam for the relief of the symptoms (congestion and pressure) associated with upper respiratory disorders.
690	Sterilization/disinfection containers	Intended to hold wrapped and/or unwrapped medical/dental devices in a chemical washer/disinfector and/or sterilizer during the washing/disinfection and/or sterilization cycle(s).
691	Sterilizer/disinfector rack	A non-sterile rack intended to hold medical devices in a steriliser or chemical washer/disinfector during the sterilisation or washing/disinfection cycle. It may also be used to transport medical devices to and from the process and for their storage. This is a reusable device.
692	Sternal binder	Intended to stabilize and support the sternum after sternotomies
693	Stress exercise trolley	This treadmill is intended to be used for cardiac stress testing.
694	Suction system filter, non sterile	A filter used with a suction system to separate tissue from the fluid waste collected from a medical procedure.
695	Surgical binoculars	Intended to be mounted onto a surgeon's spectacles to function as small telescope and provide a magnified image of the visual field during patient examination or surgical intervention.
696	Surgical camera and accessories	Intended to be used to record operative procedures.

S.No.	Device Name	Intended Use
697	Surgical camera holder	Intended to hold and position a camera, or camera system and/or other devices during surgical procedures.
698	Surgical cap, non-sterile	Intended to protect face of patient & the operating room personnel from the transfer of micro-organisms, body fluids & particulate material.
699	Surgical eye pressure shield	A non-sterile device intended to cover and mechanically protect the eyes of a patient during surgery to prevent potential ocular pressure hazards/injury associated with surgery (e.g., resulting from inadvertent pressure being applied to the eye by healthcare professionals, equipment, or due to the orientation of the patient).
700	Surgical guillotine	Intended for severing tissue as a means to prevent infection/drainage of infected site
701	Surgical helmet, non-sterile	Intended to protect healthcare workers from contaminants & debris on head.
702	Surgical implant handling forceps	A hand-held manual surgical instrument with blades designed to grasp and manipulate a surgical implant (excluding sutures) during implantation; it is not intended for use on tissues, is not a dental or ophthalmic device, and is not a dedicated tissue clip applier. This is a reusable device intended to be sterilized prior to use.
703	Surgical instrument assist arm system	The device assists in maintaining spatial positioning of instruments during surgical procedures
704	Surgical instrument holder, reusable	device intended to be used in the operating room (OR) by staff to safely contain a delicate or sharp hand-held, manual, surgical instrument(s)
705	Surgical instrument rack	Intended for the safe storage and counting of used sharps during and prior to the the end of a surgical procedure. The used sharps are held in place by foam, magnet or other mechanisms and the device can be closed securely for safe sharps disposal.
706	Surgical knee cover	Reusable surgical cover used as a protective cover to protect the patella during knee surgery.
707	Surgical lamp	Intended to provide visible illumination of the surgical field or the patient.
708	Surgical lamp (ophthalmic)	Intended to serve as a cold light source for illumination of the intraocular posterior segment in optical surgery in case of vitrectomies.

S.No.	Device Name	Intended Use
709	Surgical lens (camera accessory)	A device designed to be used with a camera, or a camera system being used during medical procedures.
710	Surgical light/illumination system/OT lights	Intended to providing optimal light and colour rendering to aid surgery.
711	Surgical material compression device	A reusable manual instrument intended to flatten material, such as tissue, for use in a surgical procedure (e.g., tympanoplasty) after it has been flattened.
712	Surgical microscope and accessories	Intended for use during surgery to provide a magnified view of the surgical field.
713	Surgical sleeve cover, non-sterile	It is a forearm covering made of non-woven synthetic fabric materials intended to be worn over a scrub suit by healthcare staff during procedures to maintain hygiene and prevent cross-contamination of microorganisms, body fluids, and particulate materials between the patient and staff.
714	Surgical torque wrench adaptor	This is a hand held component of a surgical wrench that is intended to connect to the main body of the wrench to a variety of distal end pieces (bits) and assist with the use of a torque wench in the mouth during a dental procedure.
715	Surgical trays	Intended to provide a suitable platform for general containment of many medical/surgical instruments and related items during a clinical procedure.
716	Surgical video camera	A video camera used to generate video images of surgical procedures, which are fed to a monitor screen for local or external viewing.
717	Swivel-walker	Intended to encompasses and provide support for the body of a patient who is unable to stand unassisted, to help them move (walk) by rocking sideways (shifting their weight from side-to-side with a shoulder movement).
718	Synoptophor	Intended for the evaluation and training of a patient's binocular function.
719	Tachistoscope	Intended to flash words or images at different speeds, for the purposes of ophthalmic diagnostic testing.
720	Tearable adhesive plaster	It is intended to secure dressings and for strapping on intact skin.
721	Tearable adhesive tape	It is intended to secure dressings and for strapping on intact skin.
722	Teething device, non- fluid-filled	Intended to be bitten by a patient (infant or adult) to soothe gums during the teething process.

S.No.	Device Name	Intended Use
723	Tester, colour discrimination	Devices for colour vision testing
724	Testicular temperature regulation underpants	This is a garment that is body worn that is intended to be placed around the pelvic region in the same manner as conventional male underwear that is designed to keep the testicles cool for increased spermatogenesis, as part of an fertility treatment, through ventilation features (e.g., breathable mesh) that prevent excessive insulation of the testes.
725	Therapeutic medical binder, general purpose	Intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place like abdominal, breast and perineal binder.
726	Therapeutic scrotal support	Intended for medical purposes to support the scrotum (the sac that contains the testicles)
727	Thermographic camera	It is a thermal based imaging device, intended for viewing and digitally storing thermal patterns generated by the human body in a clinic, hospital, acute care setting, surgery, healthcare practitioner facility or in any environment where healthcare is provided by a qualified healthcare professional.
728	Thermoplastic mask for immobilization	Intended to immobilize the patient to deliver the correct Radiation dose
729	Thumb spica splint	Intended to minimize movement and provide support and comfort by stabilizing an injury of the thumb
730	Toe separator	Intended to space the toes of the foot to relieve pain, pressure/friction between toes, and/or to facilitate realignment of the toes to a natural position.
731	Tongue depressor	Intended to move the tongue to facilitate examination of surrounding organs and tissue.
732	Tongue scraper	A device used to scrape the upper surface of the tongue to promote oral hygiene (e.g., to remove plaque, food debris, and bacteria, and to prevent bad breath). It may be single use or reusable and is an OTC device.
733	Tongue-retaining sleep-disordered breathing orthosis	A removable intraoral device designed to alleviate sleep-disordered breathing conditions (e.g., snoring, obstructive sleep apnoea) by retention of the tongue, frequently keeping the tongue in a forward position during sleep.

S.No.	Device Name	Intended Use
734	Tracheal surgery dilator	Intended to be used during surgical intervention of the trachea to dilate tracheal structures/passages, typically during the creation of a tracheostoma and/or for expanding the margins of a tracheostoma to assist in the insertion of a tracheostomy tube.
735	Tracheostoma protector	Intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.
736	Tracheostoma shower shield	A non-sterile, waterproof, patient-worn device intended to cover a tracheal stoma or tracheostomy tube to prevent inhalation of water during showering.
737	Tracheostomy tube holder	Intended to secure a patient's tracheostomy tube for use on pediatric (neonates, infants and children) patients.
738	Tracheostomy tube lubricant	Intended to be applied by healthcare staff or a patient to the outer surface of a tracheostomy tube inner cannula to facilitate its easy sliding into the outer cannula.
739	Tracheostomy tube neck holder, single-use	To secure a tracheostomy tube by fastening around the neck of the patient. Composed of cotton/velour and a velcro fastening.
740	Training aid for communication and speaking	Designed for the assessment of disordered voice and speech, and voice and speech therapy.
741	Training aid for perceptual sense and co-ordination	This device is an exercise system that promotes therapeutic exercises through use of one or more sensorized movement controllers. This device is indicated for use by patients with neurological or other movement impairment, typically from stroke, who are undergoing rehabilitation to facilitate muscle re-education, increased range of motion, or increased coordination.
742	Transcutaneous electrical stimulation electrode adhesive pad	Reusable gel pads that allow electrodes to adhere gently to the skin.
743	Trial frame	A device used in ophthalmic work for holding trial lenses in front of the eyes during the sight-testing procedure.
744	Truncal orthosis	Intended to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body.

S.No.	Device Name	Intended Use
745	Tuning fork	Intended to test the hearing acuity of a patient, to diagnose hearing disorders, and to test for vibratory sense.
746	Ulnar/brachial nerve protector	It is use to provide cushioning, support and protection to elbow and arms during prolonged surgeries.
747	Ultrasonic coupling gel	A coupling medium for ultrasound transmissions.
748	Ultrasonic safety goggle	Intended to be worn over the eyes to protect (shield) the healthcare worker from blood and other body fluid splashes while performing a clinical or laboratory procedure.
749	Ultrasonic scanner calibrator	It is a block of material with known properties intended to be used to calibrate ultrasonic scanning devices
750	Ultrasound imaging phantom, test object	Intended to provide a standard of reference for routine and periodic verification of ultrasound doppler imaging equipment used for the identification of disease and pathologies.
751	Ultrasound imaging system table, non-powered	A non-powered patient table designed to support and position a patient specifically for ultrasound imaging procedures.
752	Ultrasound imaging system table, powered	An electrically-powered patient table designed to support and position a patient specifically for ultrasound imaging procedures.
753	Ultrasound imaging system workstation	A freestanding image processing workstation specifically designed to be networked with one or more diagnostic ultrasound imaging systems. It is typically considered to be a component to a picture archiving and communication system (PACS) and does not contain the controls for the direct operation of the diagnostic imaging system.
754	Ultrasound imaging transducer positioning unit	A unit used to position an ultrasound system imaging transducer that is inserted into the body through an endoscope. This device is an accessory to a diagnostic ultrasound imaging system and it transmits electrical signals that, after processing, will display the position of a the transducer on a monitor.
755	Umbilical cord clamp	Used for clamping the umbilical cord after birth.
756	Umbilical ligator	Intended for umbilical cord ligation during surgical procedures.

S.No.	Device Name	Intended Use
757	Upper limbs gravity-compensating rehabilitation system	Intended to increase muscle strength, motion in different joints and improve motor function in patients who have lost their function or have restricted function in their upper extremities.
758	Urinary dilator	Intended to dilate the urinary duct
759	Urinary-incontinence vaginal insert, reusable	A non-sterile, device intended to be inserted into the vagina in order to relieve mixed or stress urinary incontinence in an adult female by providing urethral support when pressure is transferred from the abdomen to the pelvic floor area (e.g. upon coughing, laughing, sneezing, exertion).
760	Urine drainage extension tubing	A conduit for urine collection, via a pouch and tubing, into a gravity drainage collection bottle or bag.
761	Urological operating table top	A component of a modular operating table designed as a detachable table top to support a patient during urological examination and surgical procedures, including cystoscopic procedures and both transurethral and open surgery of the urinary tract.
762	Urological operating table, hydraulic/Transurethral resection table	A mobile table powered by manually-operated hydraulic mechanisms designed to support a patient during urological examination and surgical procedures, including cystoscopic procedures and both transurethral and open surgery of the urinary tract.
763	Uterine packer	Intended for introducing dressings into the uterus or vagina.
764	Vacuum cushion	Intended for positioning and re-positioning patients' head & neck, thorax, hip and full body during radiation therapy and other diseases treatment.
765	Vacuum splint	Intended to immobilize and protect injured limbs so that the patient can be transported safely and easily in emergency conditions.
766	Vaginal applicator, reusable	Intended to apply medication to the vagina.
767	Vaginal applicator, single use	A single use device intended to apply medication to the vagina
768	Vaginal exerciser/Pelvic floor muscle exerciser	Designed to provide Kegel exercises to strengthen and tone the pelvic floor muscle, which in turn improves conditions such as female incontinence, sexual dysfunction, prolapse, etc.

S.No.	Device Name	Intended Use
769	Vaginal illuminator	A device used to illuminate the vagina during a gynaecological examination or procedure.
770	Valsalva manoeuvre mouthpiece	Intended to be inserted into a patient's mouth to facilitate performance of the Valsalva manoeuvre.
771	Vice grip	Intended to hold pliers during surgical procedures.
772	Video indirect ophthalmoscope	Intended as an illumination system to direct appropriately focused light into the eye in order to obtain an intermediate image of the fundus (retina) that is viewed by the observer to diagnose the eye and record the images and videos of the patient.
773	Video intubation laryngoscope handle/monitor	Intended to enable the positioning of the blade into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation.
774	Video laryngoscope adaptor	Intended to serve as a connection between the laryngoscope and the display/monitoring device during intubation
775	Vision testing/training flipper	A device in the form of flipper lenses (two lenses on either side of a rotatable stem) intended to be used for the diagnosis and treatment of ophthalmic accommodation disorders.
776	Vision training software	A patient-interactive software package intended to use visual images (e.g., Gabor patch) to help improve vision based on noninvasive perceptual learning therapy (neuro-vision therapy), typically in patients with amblyopia, or who use corrective eyewear, or following ophthalmic surgery.
777	Visual chart	Intended for use in testing visual acuity.
778	Visual light box	Intended for use in testing visual acuity.
779	Visual projector	Intended to project an image on a screen to test visual acuity .
780	Visual field plotter	Device for visual field examination
781	Vitrectomy lenses	Intended to facilitate the visualization of the retina during Vitrectomy surgery.
782	Warming chamber	A chamber and accessories designed to warm various items prior to use, e.g. bags of irrigation or intravenous solutions, blankets, or clothing for operating theatre personnel

S.No.	Device Name	Intended Use
783	Washers for body waste receptacles	Intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan.
784	Weight activated knee joint external prosthesis	Intended as an artificial knee with a braking mechanism that prevents the knee from bending as long as the user has weight on the prosthesis
785	Weight-bearing protector for flat panel x-ray detector/film cassette	The device is a protector for a digital X-ray flat panel detector
786	Wheelchair	Intended to be used by physically disabled individuals and old age patients with limited mobility
787	Wheelchair accessory, power assisted conversion kit	A device that can only fulfil its purpose when used together with and to enhance the function of a wheelchair. It will provide the occupant/assistant with a powered driving assistance.
788	Wire tensioner	Intended to be used during orthopaedic surgery to apply an appropriate tension to a wire that is being implanted, usually as part of a system to provide corrective surgery to the spine. This is a reusable device.
789	Woven gauze pad, non-sterile	A non-medicated, non-sterile device in the form of a patch or swab (also referred to as a sponge) made from woven material (e.g., cotton, cellulose) and primarily designed to absorb fluids for medical purposes; it does not include petrolatum. It is typically used to cover/clean superficial wounds or abrasions and absorb their exudates, absorb body-surface exudates, or to apply topical medications.
790	Woven gauze roll, non-sterile	A non-sterile device in the form of a long strip of stretchable, absorbent, woven material (e.g., cotton, cellulose), wound into a roll, and typically designed for a variety of applications (non-dedicated) such as a primary wound dressing, dressing retention, injury padding and compression.
791	Woven gauze roll/sheet	A device in the form of a long length of stretchable, absorbent, woven material (e.g., cotton, cellulose), wound into a roll or folded, and typically designed for a variety of applications (non-dedicated) such as a primary superficial wound dressing, dressing retention, and injury padding and compression.

S.No.	Device Name	Intended Use
792	Wrist immobilizer	Intended to temporarily render the wrist immovable as therapy for non- displaced fractures, strains, sprains, and muscle injuries of the wrist.
793	Wrist splint	Intended to temporarily render the wrist immovable as therapy for non-displaced fractures sprains & muscle injuries of the wrist.
794	Wrist/hand/finger flexion orthosis, manual	An externally applied orthopedic appliance intended to assist in the flexion of the wrist, hand, and fingers
795	Wrist/hand/finger stable-position orthosis	An externally applied orthopaedic appliance or apparatus designed to maintain both the transverse and longitudinal arches of the hand, and to hold the thumb in a functional position. This is a reusable device
796	Wrist/hand/metacarpophalangeal joint extension orthosis	Device is designed to assist in the extension of the wrist, hand, and metacarpophalangeal joints (MP joints or knuckles)
797	X- ray marker for strut	Intended to be used in Six axis correction apparatus with software.
798	X-ray film cover	A small envelope cover used to hold and protect x-ray films that goes into a patient's mouth momentarily when taking an x-ray and then processed.
799	X-ray film magnifying glass	A convex lens used for magnifying the details of a viewed radiograph (x-ray) and shade against strong interfering light. It can be hand-held or mounted on the end of an adjustable arm (e.g., a flexible tube or an articulating arm) which is attached to a stable base or clamped to a surface worktop.
800	X-ray film processing chemical, automatic	A chemical, e.g., a fixer or developer, which is necessary for automatic processing of x-ray film or other radiographic films used in, e.g., computed tomography (CT), magnetic resonance (MR), ultrasound or nuclear medicine.
801	X-ray film processing chemical, manual	A chemical, e.g., a fixer or developer, used in the manual processing of x-ray film or other kinds of radiographic film used in medical applications, e.g., computed tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine applications.
802	X-Ray hanger	Intended to position and hold the radiograph during X ray film development, eliminate streaking and maintain alignment.

S.No.	Device Name	Intended Use
803	Y-Connector (accessory to perfusion sets)	Intended to position and hold the radiograph during X ray film development, eliminate streaking and maintain alignment.