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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, Kotla Road,
New Delhi – 110002
Dated: 26 NOV 2025

Notice

Subject: Risk classification list of medical devices pertaining to Radiotherapy - Reg.

Consequent to the publication of draft list vide File No. MED-16014(12)/1/2024-eoffice dated 06.01.2025, and in exercise of the powers conferred under sub-rule(3) of Rule 4 of the Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices pertaining to Radiotherapy, under the Medical Devices Rules, 2017.

The risk classification list of medical devices pertaining to Radiotherapy is placed in the attached **Appendix A** and it is subject to the following:

1. General intended use given against each of the devices is for the guidance of the applicants who intend to furnish applications for manufacturing/import of medical devices under the Medical Devices Rules, 2017. However, a device may have a specified intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

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

To:
All Stakeholders via CDSCO website

Appendix A

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Notice

Classification of Medical Devices Pertaining to Radiotherapy

S.No.	Device name	Intended Use	Risk Classification
1	Absorbable perirectal spacer	An absorbable perirectal spacer is composed of biodegradable material and intended to temporarily position 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 D**
2	Absorbable tissue spacer for radiotherapy	An absorbable material intended 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 tumour and normal tissue.	**Class D**
3	Accelerator system computer	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 linear or non-linear medical accelerator system and associated processing, display and analysis functions.	**Class C**
4	Accelerator system operator console	A device that is a component of a linear or a non-linear accelerator system and intended to function as the primary control panel typically for a therapeutic-use betatron or cyclotron system.	**Class C**
5	Applicator for bile duct manual brachytherapy	A manual brachytherapy applicator specifically intended 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 bile duct.	**Class C**
6	Applicator for bile duct remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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**
7	Applicator for bladder manual brachytherapy	A manual brachytherapy applicator intended 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**
8	Applicator for bladder remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended to be temporarily implanted in the bladder and serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites.	**Class C**

9	Applicator for brachytherapy non- central circulatory general-purpose, manual	A general-purpose brachytherapy applicator intended 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**
10	Applicator for brachytherapy non- central circulatory general-purpose remote, after loading	A general-purpose remote controlled 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 non-central circulatory system.	**Class C**
11	Applicator for bronchial manual brachytherapy applicator	A manual brachytherapy applicator specifically intended 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.	**Class C**
12	Applicator for bronchial remote after loading brachytherapy	A remote controlled brachytherapy applicator specifically 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 in the bronchus.	**Class C**
13	Applicator for cervical/endometrial manual brachytherapy	A manual brachytherapy applicator specifically intended to facilitate manual placement (puncture, placement with an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in uterine, cervical or intrauterine region.	**Class C**
14	Applicator for Cervical/endometrial remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically 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 in the uterus, cervix and endometrium.	**Class C**
15	Applicator for esophagus manual brachytherapy	A manual brachytherapy applicator specifically intended 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.	**Class C**
16	Applicator for esophagus remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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.	**Class C**
17	Applicator for eye manual brachytherapy	A manual brachytherapy applicator specifically intended to facilitate manual, temporary placement of brachytherapy source, to the eye surface.	**Class C**
18	Applicator for eye remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended for eye radiation therapy. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources.	**Class C**

19	Applicator for nasopharynx manual brachytherapy	A manual brachytherapy applicator specifically intended 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**
20	Applicator for nasopharynx remote after loading brachytherapy	A remote controlled 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 in the nasopharynx.	**Class C**
21	Applicator for neck manual brachytherapy	A manual brachytherapy applicator specifically intended 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**
22	Applicator for neck remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically 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**
23	Applicator for pancreas manual brachytherapy	A manual brachytherapy applicator specifically intended 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.	**Class C**
24	Applicator for pancreas remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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**
25	Applicator for prostate manual brachytherapy	A manual brachytherapy applicator specifically intended 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.	**Class C**
26	Applicator for prostate remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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**
27	Applicator for rectal/anal manual brachytherapy	A manual brachytherapy applicator specifically intended 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**
28	Applicator for rectal/anal remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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**

29	Applicator for tongue manual brachytherapy	A manual brachytherapy applicator specifically intended 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.	**Class C**
30	Applicator for tongue remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically intended 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**
31	Applicator for vaginal manual brachytherapy	A manual brachytherapy applicator specifically intended 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 vaginal/transvaginal regions.	**Class C**
32	Applicator for vaginal remote after loading brachytherapy	A remote-controlled brachytherapy applicator specifically 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 in the vagina.	**Class C**
33	Blood vessel manual brachytherapy applicator	A manual brachytherapy applicator intended exclusively for blood vessel radiotherapy by facilitating manual placement (placement and removal under endoscopy or using an image diagnostic system) of single or multiple therapeutic radiation sources in the treatment site to prevent formation of plaque, stenosis and restenosis in blood vessels after surgery.	**Class D**
34	Blood vessel remote after loading brachytherapy applicator	A remote-controlled brachytherapy applicator intended exclusively 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**
35	Brachytherapy needle	A sterile, sharp bevel-edged, hollow tubular metal instrument that is intended to inject radionuclide into a body cavity or tissue as a source of nuclear radiation for cancer therapy (brachytherapy).	**Class B**
36	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 intended to simulate the functional, physical, or a combination of these characteristics of normal or diseased human organs.	**Class B**
37	Brachytherapy system chair	A mains electricity (AC-powered) device (a chair or stool) that is a component of a brachytherapy system and specifically intended 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**

38	Brachytherapy system remote afterloading source transfer tube	The transfer tube, when attached to the applicator and the after loading system, is intended to provide 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**
39	Brain manual brachytherapy applicator	An applicator specifically intended 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**
40	Brain remote after loading brachytherapy applicator	A remote-controlled brachytherapy applicator intended 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**
41	Breast brachytherapy system applicator, manual	A manual brachytherapy applicator specifically intended for use in radiation therapy treatments of the breast.	**Class C**
42	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically intended for use in radiation therapy treatments of the breast.	**Class C**
43	Breast ductography cannula	A sterile, semi-rigid or rigid metal tube that is intended to be 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 B**
44	Central circulatory general-purpose manual brachytherapy applicator	A single or module applicator intended 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**
45	Central circulatory general-purpose remote after loading brachytherapy applicator	Intended to be temporarily implanted in the body, to serve 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**
46	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.	**Class D**
47	Central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system intended 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.	**Class D**

48	Central circulatory remote after loading brachytherapy therapeutic radionuclide source	A device for the central circulatory system intended for use as radiation source to deliver a high or low dose rate with a remote after-loading brachytherapy device for radiotherapy.	**Class D**
49	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**
50	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.	**Class D**
51	Compact thermoluminescent dosimetry electrometer	Thermoluminescence dosimeter (TLD) is intended to measure the radiation dose emitted to the phantom, and/or other organs, such as eyes that have high radiosensitivity.	**Class A**
52	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. Not intended for use in central circulatory or central nervous system.	**Class C**
53	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**
54	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**
55	Fluoroscopy/angiography table, powered	A powered table intended 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 is not dedicated to breast biopsy, and is not intended for other specialized surgeries.	**Class B**
56	Gamma knife for radiotherapy/surgery	A set of devices that are intended to apply 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**

57	General-purpose brachytherapy system applicator, manual	A general-purpose brachytherapy applicator intended to facilitate delivery of radiation therapy treatments that are not specific to a particular anatomical region. Not intended for central-circulatory/central nervous system use.	**Class C**
58	General-purpose brachytherapy system applicator, remote-afterloading	A general-purpose remote-afterloading brachytherapy applicator intended to facilitate the delivery of radiation therapy treatments in a range of anatomical regions (e.g., liver, kidneys, lungs, gastrointestinal tract). Not intended for central circulatory/central nervous system use.	**Class C**
59	High-frequency hyperthermia system	A system intended to generate high-temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumours, or other diseases. Not intended for use in direct contact with central circulatory or central nervous system.	**Class C**
60	Interventional radiology percutaneous-access kit	A collection of various instruments/ devices (e.g., introducer sheath, dilator, guides, cannula, needle) 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]. It does not contain pharmaceuticals.	**Class B**
61	Intra-vaginal organ positioning device for diagnostic imaging and radiotherapy	A device that is specifically intended 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**
62	Laser irradiation therapy kit	A kit intended to be used during laser irradiation. It may include a puncture needle, a guide wire, and a guiding sheath for guiding probes, etc. This does not include laser irradiation devices.	**Class B**
63	Linear accelerator system	An assembly of devices intended to produce high-energy electrons to yield high-energy x-rays used for therapeutic applications, primarily to treat cancer.	**Class C**
64	Living tissue radiotherapy system	A low energy X-ray therapy system intended 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**
65	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. 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**

66	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. These sources come in a variety of forms, e.g., encapsulated, sealed, plated, foil or embedded sources. Not intended for use in central circulatory/central nervous system.	**Class C**
67	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 for either permanent or temporary delivery at the topical, interstitial, intraluminal, or intracavitary brachytherapy treatment site. This is not intended for use in direct contact with the central-circulatory or central nervous system.	**Class C**
68	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**
69	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 B**
70	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**
71	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**
72	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.	**Class C**
73	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**
74	Non-central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device which is histocompatible 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**

75	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**
76	Non-central circulatory remote afterloading brachytherapy therapeutic radionuclide source	A device for the non-central circulatory system used as radiation source intended to deliver a high or low dose rate with an after-loading brachytherapy device for radiotherapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor.	**Class C**
77	Non-central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A non-central circulatory 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**
78	Non-linear accelerator system	An assembly of devices intended to use a strong magnetic field to produce a non-linear acceleration path for particles accelerated in an alternating electric field and used therapeutically, primarily in the treatment of cancer.	**Class C**
79	Patient positioning device for breast diagnostic imaging and radiotherapy	A device that is specifically intended to properly position and fix a female patient's breasts and chest for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
80	Patient positioning device for extremity diagnostic imaging and radiotherapy	A device that is specifically intended to properly position and fix a patient's arms and legs for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
81	Patient positioning device for pelvis diagnostic imaging and radiotherapy	The device that consists of frames, plates, or other parts, and is specifically intended to properly position and fix the patient's abdomen and pelvic region for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
82	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 intended to properly position and fix the patient's whole body for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy.	**Class B**
83	Patient Positioning System, Ultrasound	An assembly of devices intended 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**
84	Post Breast Biopsy Hemostatic Breast Compression Device	A noninvasive, nonpowered device intended to achieve and maintain hemostasis of a breast biopsy wound site by compression.	**Class B**

85	Powered neutron therapy table	A programmable bed for radiotherapy intended 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**
86	Powered patient table for accelerator	A bed for electric radiotherapy intended to adjust the patient's posture and immobilize the patient for radiotherapy that uses medical linear accelerator or non-linear accelerator.	**Class B**
87	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**
88	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**
89	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**
90	Powered X-ray radiation therapy table	A programmable electrically operated bed for radiotherapy intended to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus.	**Class B**
91	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**
92	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). It may also have an x-ray source to generate higher quality images.	**Class C**

93	Radiation therapy simulation system	A radiation therapy simulation system is 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 by a specific set of treatment parameters. It is configured as a diagnostic x-ray system, e.g., fluoroscopic, planar, computed tomography (CT), etc., with associated hardware and software intended for radiation therapy treatment planning.	**Class C**
94	Radiation therapy system workstation, multi-purpose	A freestanding, multi-purpose, image processing device that can be a component of one or more radiation therapy systems, e.g., teletherapy, brachytherapy or linear accelerator. It does not contain the controls for the direct operation of the radiation therapy system. It can receive and transmit data both on-line and off-line and is configured to provide the capability to remotely process, manipulate and view patient images/information used in patient treatment.	**Class B**
95	Radiological image marker, implantable	A device intended to be implanted within the body temporarily or permanently to create identifying marks that can be seen on radiographic film or digital images. It is used to locate and delineate a tumour, lesion, or other site of interest. It may be intended for use during radiotherapy procedures.	**Class C**
96	Radiological image marker, implantable, bioresorbable	A bioresorbable device intended to be implanted permanently within the body to create identifying marks that can be seen on radiographic film or digital images. It is used to locate and delineate a tumour, lesion, or other site of interest. It may be intended for use during radiotherapy procedures.	**Class D**
97	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**
98	Radionuclide dynamic function testing equipment	A device intended 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**

99	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**
100	Radionuclide source for remote irradiation therapy	Radiation sources generated in a reactor and used as in a remote after loading system intended to deliver a therapeutic radiation beam to a target anatomical area. Not intended for use in central circulatory or central nervous system.	**Class C**
101	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**
102	Real-time position management respiratory gating system, optical	An assembly of electronic devices intended 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 may also be utilized for breath-hold monitoring during radiotherapy.	**Class C**
103	Rectal balloon for prostate immobilization	This is a single use, inflatable, non-powered positioning device intended to be placed in the rectum to immobilize the prostate in patients undergoing radiation therapy.	**Class B**
104	Remote controlled radionuclide applicator system, general-purpose	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**
105	Remote-afterloading brachytherapy system, general purpose	An assembly of devices using a remotely-controlled radioactive source transport system intended 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**
106	Source safe for Brachytherapy remote afterloading system	A component of a remote afterloading brachytherapy system consisting of a shielded vault, and associated source retraction and extrusion mechanisms, alarms, and related mechanical, electronic and software controls, intended 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**

107	Stereotactic radiosurgical system	An assembly of devices intended 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.	**Class C**
108	Stereotactic radiotherapy linear accelerator system	An assembly of devices intended for treatment based on a linear accelerator (or microtron). The device may be used to inactivate lymphocytes.	**Class C**
109	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 intended to position and support a patient during treatments administered using a therapeutic radionuclide teletherapy system (e.g., a Cobalt-60 teletherapy system). It can be a stationary or mobile unit, or incorporated as an integral component of a radionuclide teletherapy system or gantry configuration.	**Class B**
110	Teletherapy radionuclide system, conventional/Cobalt therapy machine	A stationary assembly of computer-based devices intended 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**
111	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**
112	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.	**Class C**
113	Ultraviolet Photopheresis system blood set	A collection of devices intended for use 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**

114	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 intended to irradiate blood components during extracorporeal photoimmunetherapy to treat immune disorders, especially cutaneous T-cell lymphoma (CTCL).	**Class C**
115	X-ray CT system for radiotherapy planning	An X-ray CT system intended to be 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**
116	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**
117	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**
118	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**
119	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.	**Class C**