

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

Notice

File No. 29/Misc./03/2020-DC (146)

Date: 26 JUL 2021

Subject: Classification of Medical Device pertaining to Interventional Radiology under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, sale and distribution, clinical investigation, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (F) dated 31.01.2017 which is already implemented from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices, based on the intended use, risk associated with the device and other parameters specified in the First Schedule of the Medical Devices Rules-2017

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic in nature and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.



(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

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Classification of Medical Devices Pertaining to Interventional Radiology

S.No.	Medical Device Name	Intended Use	Risk Class
1	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.	A
2	Positron camera	A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body.	A
3	Nuclear whole body counter	A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body.	A
4	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.	C
5	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.	B
6	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	C
7	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.	C
8	Nuclear rectilinear scanner	A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient.	A
9	Nuclear tomography system	A nuclear tomography 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.	C
10	Nuclear uptake probe	A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region	A
11	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.	A
12	Nuclear scanning bed	A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.	A
13	Radionuclide dose calibrator	A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients	B
14	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).	C
15	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.	A
16	Nuclear electrocardiograph 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	A

17	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	B
18	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.	B
19	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.	B
20	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.	B
21	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.	C
22	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	C
23	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 image intensifier	C
24	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.	C
25	Radiographic film marking system	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.	A
26	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.	C
27	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-radiation into a visible image.	C
28	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	B
29	Diagnostic x-ray high voltage generator	A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes.	A
30	Mammographic x-ray system	A mammographic x-ray system is a device intended to be used to produce radiographs of the breast	C

31	Photofluorographic x-ray system	A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body	C
32	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.	A
33	Diagnostic x-ray tube mount	A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.	A
34	Pneumoencephalographic chair	A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).	B
35	Radiologic patient cradle	A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.	A
36	Radiographic film	Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.	A
37	Radiographic film 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	B
38	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.	B
39	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.	B
40	Wall-mounted radiographic cassette holder	A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use	A
41	Radiographic film illuminator	A radiographic film illuminator is a device containing a visible light source covered with a translucent front that is intended to be used to view medical radiographs	A
42	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.	C
43	Radiographic 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	A
44	Radiographic head holder	A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.	A
45	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.	A
46	Radiographic intensifying screen	A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident x-ray photons into visible light and intended for medical purposes to expose radiographic film.	A
47	Radiographic ECG/respirator synchronizer	A radiographic ECG/respirator 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.	A

48	Radiologic table	A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.	A
49	Transilluminator for breast evaluation	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.	D
50	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.	A
51	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.	C
52	Medical image analyzer	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, is a prescription device that is 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.	B
53	Radiological computer aided triage and notification software	Radiological computer aided triage and notification software is an image processing prescription device 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.	C
54	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.	C
55	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.	C
56	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.	C

57	Foetal cardiac monitor	A mains electricity (AC-powered) device designed to detect, measure, and display foetal heart activity during the perinatal period.	C
58	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.	C
59	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.	B
60	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.	B
61	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.	B
62	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.	B
63	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.	B
64	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.	B
65	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).	C
66	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).	B