

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

Notice

File No. 29/Misc./03/2020-DC (180)

Date: **06 AUG 2021**

Subject: Classification of Medical Device pertaining to Radiotherapy 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 (E) 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

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NOTICE

Classification of Medical Devices Pertaining to Radiotherapy

| Sr. No. | MEDICAL DEVICE NAME | INTENDED USE | RISK CLASS |
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| 1 | 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. | C |
| 2 | 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. | C |
| 3 | 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. | D |
| 4 | 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. | 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. | C |

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| 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. | C |
| 7 | Applicator for brachytherapy bile duct remote after loading | 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. | C |
| 8 | Applicator for brachytherapy Cervical/endometrial remote after loading | 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 uterine cervix and endometrium. | C |
| 9 | 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. | C |
| 10 | 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. | C |

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| 11 | 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. | C |
| 12 | 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. | 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. | C |
| 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. | 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. | C |
| 16 | Applicator for manual cervical/endometrial 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. | C |

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| 17 | Applicator for manual rectal/anal 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. | C |
| 18 | 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. | C |
| 19 | 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. | C |
| 20 | 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. | C |
| 21 | 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. | C |
| 22 | 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. | C |
| 23 | 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. | C |

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| 24 | 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. | C |
| 25 | 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. | C |
| 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. | 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. | 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. | 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. | C |
| 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. | C |

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| 31 | Bile duct brachytherapy system applicator, remote-after loading | A remote after loading brachytherapy applicator specifically designed for use in radiation therapy treatments of the bile duct. It is designed for temporary insertion into the bile duct and serve as a guide for computer-controlled placement and removal of single or multiple radioactive sources. | C |
| 32 | Bladder brachytherapy system applicator, manual | A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the bladder. | C |
| 33 | 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. | D |
| 34 | 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. | D |
| 35 | 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). | 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 designed to simulate the functional, physical, or a combination of these characteristics of normal or diseased human organs. | B |
| 37 | 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. | B |
| 38 | 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. | C |

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| 39 | 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. | C |
| 40 | Brain brachytherapy system applicator, remote-after loading | A remote after loading brachytherapy applicator specifically designed for use in radiation therapy treatments of the brain. It is designed for temporary implantation within the body and serve as a guide for computer-controlled placement and removal of single or multiple radioactive sources in the brain. | C |
| 41 | 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. | D |
| 42 | 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. | D |
| 43 | 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. | C |
| 44 | 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. | D |
| 45 | 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. | 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. This device does not equip a remotely controlled radiation source transporter. | D |

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| 47 | 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. | D |
| 48 | 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. | 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. | 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. The radiation source, which is temporarily inserted manually, is supplied in various forms – e.g., encapsulated, sealed, plated, foiled, or embedded. | D |
| 51 | 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. | 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. | C |
| 53 | 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. | C |
| 54 | 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. | B |

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| 55 | 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. | B |
| 56 | Light beam patient position indicator | A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. | A |
| 57 | 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. | C |
| 58 | Manual radionuclide applicator system | A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. | A |
| 59 | Medical neutron radiation therapy system | A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy | C |
| 60 | 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. | B |
| 61 | 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. | C |
| 62 | 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. | C |
| 63 | 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. | C |

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| 64 | 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. | C |
| 65 | 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. | C |
| 66 | Non-powered accelerator system table | A mechanically-operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses a medical linear accelerator or non-linear accelerator. | A |
| 67 | Non-powered neutron therapy table | A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from a nuclear reactor, etc. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical table top positioning control and table height control. | A |
| 68 | Radionuclide brachytherapy table | A programmable bed for electric radiotherapy 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. | B |
| 69 | Non-powered remote irradiation therapy table | A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus. | A |
| 70 | Non-powered X-rays radiation therapy table | A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus. | A |
| 71 | Operator radiation protection spectacles | A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment. | B |
| 72 | 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. | B |
| 73 | 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. | B |
| 74 | 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. | B |

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| 75 | 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. | B |
| 76 | Post Breast Biopsy Hemostatic Breast Compression Device | Intended to achieve and maintain hemostasis of a breast biopsy wound site. | C |
| 77 | 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. | B |
| 78 | 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. | B |
| 79 | 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 | C |
| 80 | 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. | B |
| 81 | 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. | B |
| 82 | 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. | B |
| 83 | 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 | C |
| 84 | 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. | C |
| 85 | Radiographic Protective Glove | A personnel protective glove is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation | B |

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| 86 | 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 | C |
| 87 | 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. | B |
| 88 | 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. | C |
| 89 | 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. | C |
| 90 | 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. | C |
| 91 | 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. | C |
| 92 | 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. | C |
| 93 | 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. | C |
| 94 | Stationary radiation protection barrier | A device for permanent installation that forms a structural barrier that shields or attenuates radiation emitted from primary radiation source or scattered radiation source. | B |
| 95 | 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. | C |
| 96 | 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. | C |

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| 97 | 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. | C |
| 98 | X-ray/CT combined linear accelerator system | A combined system of a linear accelerator system and an X-ray CT system for radiotherapy planning. | C |
| 99 | X-ray/CT combined particle radiotherapy equipment | A combined system of particle radiotherapy equipment and an X-ray CT system for radiotherapy planning. | C |
| 100 | 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. | C |
| 101 | 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 is indicated. The system operates on the principle of linear acceleration of electrons, providing a predictable radiation field in a beam of well-defined dimensions | C |