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

Notice

File No. 29/Misc./03/2020-DC (153) – Part 1 **Date:** 11 OCT 2022

Subject: Classification of medical device pertaining to Oncology 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 for their with respect to the import, manufacture, clinical investigation, sale and distribution, 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 are to be commence 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, Appendix A. based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated 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 and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

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Drugs Controller General (India)

To,

1. CDSCO Website

Appendix A

File No. 29/Misc/03/2020-DC (153) – Part 1
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA, Bhawan, New Delhi-110002

Notice

Classification of Medical Devices Pertaining to Oncology

S. No.	Medical Device Name	Intended Use	Risk class
1	FerriScan R2-MRI Analysis System	The FerriScan R2-MRI Analysis System is intended to measure liver iron concentration to aid in the identification and monitoring of non-transfusion dependent thalassemia patients receiving therapy with deferasirox.	C
2	Alternating electric field antimitotic cancer treatment system generator	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
3	Alternating electric field antimitotic cancer treatment system transducer array	Alternating electric fields therapy is a novel anticancer treatment that disrupts tumor cell mitosis.	C
4	Bladder instillation buffer solution	A sterile buffer solution intended to be used exclusively for bladder instillation to help create an optimal environment necessary for the effective treatment of superficial bladder cancer with a chemotherapy agent.	B
5	Breast 3-D infrared imaging/vascular analysis system	An assembly of mains electricity (AC-powered) devices intended for three-dimensional (3-D) breast imaging and breast vascular analysis, typically used with mammography screening to perform a breast cancer risk examination.	C
6	Colonic cytology sampling set	A collection of non-sterile devices intended to collect exfoliated colonic cells (colonocytes) from the surface of human rectal mucosa for colorectal cancer investigation and/or patient screening.	B
7	Cryosurgical set	A sterile collection of disposable devices used in conjunction with a cryosurgical unit as well as monitoring and other devices to perform a surgical technique that involves freezing a targeted area of tissue to damage and destroy cancer cells in the unwanted portions.	C
8	Capsular tension ring	A circular band intended to be used to enhance the mechanical stability of a subluxated crystalline lens capsule in the presence of weak or absent supporting zonules.	C
9	Electro cancer therapy system	An assembly of devices designed for the treatment of tumours and the destruction of their cancerous cells using low-voltage direct current of small intensity delivered via electrodes placed across the affected body area.	C

10	Electronic clinical breast examination system	A portable assembly of devices designed to electronically measure, map, document and store information about breast lesions/masses with regard to shape, size, location, consistency/relative hardness during a clinical breast examination (CBE)	B
11	Endocervical aspirator	A collection of devices designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually-powered suction.	C
12	Alternating electric field antimitotic cancer treatment system	An assembly of portable devices designed to apply low-intensity, intermediate-frequency (100-300 kHz) alternating electric fields to treat certain forms of recurrent or newly-diagnosed cancer; typically glioblastoma multiforme (GBM) [malignant brain tumour].	D
13	Balloon kyphoplasty kit	A collection of sterile surgical instruments and devices used for the reduction of a vertebral compression fractures (VCFs) caused by trauma, cancer, or osteoporosis during a minimally invasive procedure commonly known as balloon kyphoplasty.	C
14	Accelerator system chair	A seat, typically with legs, that is a component of a therapeutic accelerator system, and used to support and position a seated patient during radiation therapy treatments involving the use of either a medical linear accelerator or non-linear accelerator.	C
15	Accelerator system quality assurance device	An instrument specifically designed to be used to check the calibration and performance of linear and non-linear medical accelerator systems used for radiation therapy applications, for quality assurance (QA) purposes	C
16	Acupressure wristband	A device designed to be worn on the wrist(s) for the application of pressure to the Nei-kuan (P6) acupressure point, the area identified to help relieve the sensation of nausea.	B
17	Anorectal brachytherapy system applicator, manual	A manual brachytherapy applicator specifically designed to be used in radiation therapy treatments of the rectum and/or anus.	C
18	Anorectal brachytherapy system applicator, remote-afterloading	A remote afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the rectum and/or anus.	C
19	Antimicrobial postsurgical brassiere	A woman's undergarment which includes antimicrobial properties designed to support and/or contour the breast(s) or hold a dressing in place after surgical intervention (e.g. thoracic surgery, mastectomy, lumpectomy)	A
20	Antimicrobial postsurgical female underpants	It is intended for use during medical treatment (e.g., chemotherapy) or be used to protect the skin following treatment with a medication (e.g. ointment, cream). It is specifically designed for patient support/comfort in the home or healthcare facility. This is a reusable device.	A
21	Blood photochemical treatment agent	A sterile photochemical agent (psoralen) intended to be used in conjunction with ultraviolet A (UVA) irradiation to eliminate nucleated cells from blood or blood components (e.g. plasma, leukocyte-enriched blood fraction).	C
22	Brachytherapy radionuclide phantom, test object	A non-tissue configured model designed to mimic the functional/physical characteristics of normal or diseased human organs during performance evaluations of brachytherapy system	A

		components or radiation therapy treatment planning devices.	
23	Brachytherapy source spacer	A sterile, bioabsorbable device designed to separate radioactive sources of the seed type that are permanently implanted in close proximity to a selected localized tumour, to increase the distribution of radioactivity to the tumour.	C
24	Brachytherapy system remote-afterloading operator console	A mains electricity (AC-powered) component of a remote-afterloading brachytherapy system intended to function as the primary control panel for the remote afterloader. It typically includes hardware and software that allows for information display and/or transfer, data processing, analysis, and information archiving functions; it may also be intended to interface with other devices (e.g., radiation therapy treatment planning computer) as part of a picture archiving and communication system (PACS).	C
25	Breast binder	A strip or roll of fabric or plastic material applied to the breast or breasts for soft tissue support. This is a single-use device.	A
26	Breast brachytherapy system applicator, remote-afterloading	A sterile, remote-afterloading brachytherapy applicator specifically designed for use in radiation therapy treatments of the breast. It is typically designed for temporary implantation within the breast and serves as a guide for computer-controlled placement and removal of single or multiple radioactive sources. Included are various types of applicators such as hollow needles, tubes, or catheters, and their associated components. This is a single-use device.	C
27	Breast transilluminator	A mains electricity (AC-powered) transilluminating device with a built-in light source using low intensity emissions of visible light and near-infrared radiation (700 to 1050 nm) that is transmitted through the female breast to visualize translucent tissue for the diagnosis of cancer, or other conditions, diseases or abnormalities. This device may also be known as a diaphanoscope.	A
28-a	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for intracorporeal (endosonography or endoscopic) ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast.	C
28-b	Breast ultrasound imaging system	An assembly of mains electricity (AC-powered) devices designed for extracorporeal ultrasound imaging procedures involving the breast. It typically includes special imaging tables used to optimize the ability to give reproducible images of the breast	B
29	Cervical cone knife	A surgical, manually-operated, instrument that is inserted into the vagina and designed for excising a sample of abnormal tissue, e.g., indicated by the presence of precancerous changes, from the cervix.	C
30	Cervical cytology scraper, reusable	blunt surgical instrument used to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a reusable device.	A
31	Cervical cytology scraper, single-use	A hand-held, manual, blunt surgical instrument designed to scrape and retrieve cytological material from the surface of the cervix (neck of the uterus) or vaginal area for pathological examination and diagnosis, often for the detection of cervical cancer. This is a single-use device.	B

32	Coronary artery brachytherapy system applicator, manual-afterloading	A sterile flexible tube intended to deliver/remove radiation therapy sources into a coronary artery, typically into the lumen of an implanted stent, as part of a manual-afterloading brachytherapy system. It is introduced into the patient and subsequently connected to the brachytherapy system source transfer device; it includes radiopaque markers to monitor the position of the radiation source. Disposable devices associated with the procedure may be included (e.g., syringe, connectors). This is a single-use device.	D
33	Cytotoxic waste receptacle	A device designed as a container to allow the safe deposit, collection and storage of cytotoxic materials (e.g., chemotherapy/antineoplastic drugs).	A
34	Electroporation therapy system	A mobile assembly of devices designed to apply electrical impulses to the tissue to enable electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)] and genetic materials [electrogenetherapy (EGT)], to reach the cytoplasm.	C
35	Electroporation therapy system endoscopic applicator	A sterile, patient-contact component of an electroporation therapy system intended to fit onto the distal tip of an endoscope and connect to an electroporation therapy system generator to deliver electrical impulses to tissues during endoscopy as part of electroporation, a phenomenon that induces alteration in the structure of cell membranes to increase their permeability and allow molecules that usually cannot enter the cell membrane, such as drugs [electrochemotherapy (ECT)], to reach the cytoplasm.	C
36	Externally-propelled flexible video colonoscope	A non-sterile endoscope with a highly flexible sleeve and distal tip intended for the visual examination of the entire adult colon [lower gastrointestinal (GI) tract].It is used for the screening of colorectal cancer and the detection of other diseases of the lower GI tract. This is a single-use device.	B
37	Extravascular-circulation hyperthermia system	An assembly of devices designed to produce and control heated fluids circulated within a vessel applied to the body (e.g., vest, mattress, jacket, band, pad, body wrap, catheter, probe) for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions.	B
38	Extravascular-circulation hyperthermia system applicator, extracorporeal	A vessel applied to the outside of the body (e.g., in the form of a jacket, vest, body wrap, cushion, blanket, or mattress) that incorporates tubing through which heated fluids are circulated for systemic or localized heating to treat malignant tumours, benign growths, or other disease-related conditions. he applicator typically includes a thermometry component that monitors the temperature of the applicator during operation. The applicator includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a reusable device.	A
39	Extravascular-circulation hyperthermia system applicator, intracorporeal	A component of a hyperthermia system that typically consists of catheter-enclosed tubing which is introduced into the body either manually or endoscopically. Heated fluid is circulated through the applicator's tubing for localized heating to treat malignant tumours, benign growths, or other disease-related conditions. The applicator	C

		(also called an interstitial applicator or probe) typically includes a thermometry component that monitors the temperature of the applicator during operation; it also includes tubing, cables, and connectors that interface with the hyperthermia system's control unit during treatments. It is typically used in an oncology department. This is a single-use device.	
40	Facial prosthesis	An externally-applied device intended to be used as an artificial substitute for parts or sections of the face [e.g., nose, eye(s), eye brows, upper lip] to help restore facial appearance.	B
41	Fixed-aperture therapeutic x-ray system collimator	A non-automated, x-ray beam-limiting device that is a component of a therapeutic x-ray system and whose opening size/length/shutter assembly is fixed. It is used in radiation therapy applications to limit the effects of scattered radiation and to protect the patient by limiting or eliminating exposure to non-target body areas during treatment. This device is specifically designed for use with an x-ray simulation or therapeutic x-ray system.	C
42	Flexible fibre optic bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
43	Flexible fibre optic mediastinoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the mediastinum (the intrapleural space located behind the sternum). It is inserted into the body through an artificial orifice created by an incision made during mediastinoscopy. Anatomical images are transmitted to the user by the device through a fibre optic bundle. This device is commonly used to examine structures such as lymph nodes during a staging evaluation of lung cancer, or to establish the diagnosis of a tumour that is localized to the mediastinum. This is a reusable device.	C
44	General-purpose infusion pump, mechanical, single-use	A portable, non-electric, mechanically-powered device designed to be operated by healthcare professionals for dispensing a single dose of fluid medication (e.g., for antibiotic therapy, chemotherapy, analgesia). It consists of an empty reservoir intended to be filled with medication, a flow-rate regulator and a non-sterile (sterilizable) administration line intended to be connected to an infusion catheter (not included) for intravenous (IV), subcutaneous, intramuscular, or epidural administration. It may include flow and fluid level mechanical indicators and may be worn by the patient in and outside of healthcare settings. This is a single-use device.	C
45	Flexible ultrasound bronchoscope	An endoscope with a flexible inserted portion intended for the visual examination and treatment of the trachea, bronchi, and lungs. It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by the device typically through a fibre optic bundle or a video system, and an ultrasound probe. The probe may be built-in or inserted through a dedicated lumen so that its	B

		distal tip is positioned adjacent to that of the endoscope. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	
46	General-purpose infusion pump, mechanical, reusable	A non-electric, mechanically-powered (e.g., a spring mechanism) device designed for the continuous or intermittent infusion of medication, typically for antibiotic therapy, chemotherapy, or pain management by intravenous (IV), subcutaneous, intramuscular, or epidural routes. It is primarily designed to be worn by the patient during ambulation in the home. It may be used for patient-controlled analgesia (PCA), and may include mechanical indicators for flow and fluid level status. This is a reusable device.	C
47	Flexible video bronchoscope, reusable	An endoscope with a flexible inserted portion for endoscopic procedures of the airways and tracheobronchial tree (i.e., bronchoscopy). It is inserted through the mouth or nose during bronchoscopy. Anatomical images are transmitted to the user by a video system with a charge-coupled device (CCD) chip at the distal end and the images showing on a monitor. It is commonly used to diagnose lung infections, pneumonia, or lung cancer, and allows physicians to view the insides of the lungs and take biopsies and samples of secretions. This is a reusable device.	B
48	Robotic Guidance system for image Guided procedures	The Medical Device is an accessory to an imaging system (CT, CT-PET) intended for the spatial positioning and orientation of an instrument guide. A surgeon then manually advances one or more instruments for percutaneous image guided interventional procedures through the instrument guide. The device is not intended to make any contact with the patient.	B