

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

NOTICE

File No. 29/Misc./03/2020-DC (193)

Date: 13 SEP 2021


Subject: Classification of medical device pertaining to General Hospital 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 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 (E) 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 based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

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.


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

To,

1. CDSCO Website

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

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Classification of Medical Devices Pertaining to General Hospital

S. No.	Device Name	Inteded Use	Risk Class
1	Liquid crystal forehead temperature strip	A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes.	B
2	Bed exit monitor, Fall prevention	Intended to be placed under mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.	A
3	Electronic monitor for gravity flow infusion systems	Inteded to electronically monitor the amount of fluid being infused into a patient.	C
4	Electrically powered spinal fluid pressure monitor	Inteded to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal.	B
5	Spinal fluid manometer	A spinal fluid manometer is a device used to measure spinal fluid pressure using needle and graduated column.	B
6	Stand-on patient scale	Intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform.	A
7	Patient scale	A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scaleby placing scale under a bed or chair to weigh both the support and the patient.	A
8	Sterilization process indicator (Biological)	A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization on medical device.	B

9	Sterilization process indicator (Physical/chemical)	A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process on medical device.	B
10	Clinical color change thermometer.	A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature.	A
11	Apgar timer.	The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.	A
12	Hydraulic adjustable hospital bed.	Intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
13	Manual adjustable hospital bed.	A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
14	Pediatric medical crib.	Intended for medical purposes for use with a pediatric patient.	B
15	Medical bassinet.	Intended for medical purposes in hospital for use (birth to approximately 5 months of age) in a nursery, labor and delivery unit, or patient room.	B
16	Nonpowered flotation therapy mattress.	A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials, to treat or prevent decubitus ulcers (bed sores).	A
17	Therapeutic medical binder.	Intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place like abdominal, breast and perineal binder.	A
18	Burn sheet.	Inteded to wrap around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants	A
19	Neonatal eye pad.	A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.	A
20	Pressure infusor for an I.V. bag.	Device inteded to inflate and increases the pressure on the I.V. bag to assist the infusion of the fluid	B

21	Intravascular administration set, automated air removal system.	Inteded to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid.	B
22	Patient care reverse isolation chamber.	Device inteded protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality.	B
23	Jet lavage.	A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid.	B
24	Patient lift, Electrcially powered	Inteded to lift and transport patients in hsoptial in the horizontal or other required position from one place to another, as from a bed to a bath.	B
25	Nipple shield.	A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman.	A
26	Lamb feeding nipple.	A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities	A
27	Suction snakebite kit.	Intended for removing venom from the wound.	A
28	Chemical cold pack snakebite kit.	Intended for first-aid treatment of snakebites	D
29	Therapeutic scrotal support.	Intended for medical purposes to support the scrotum (the sac that contains the testicles)	A
30	Cardiopulmonary resuscitation board.	Intended to be placed under a patient to act as a support during cardiopulmonary resuscitation.	A
31	Ultrasonic cleaner for medical instruments.	Intended for cleaning medical instruments by the emission of high frequency soundwaves	B
32	Medical insole.	Intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.	A
33	Ingestible event marker.	An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.	C
34	Remote Medication Management System.	The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional.	B

35	Medical examination light, AC powered or Battery	Intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.	A
36	Skin pressure protectors.	A skin pressure protector is a device intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores)	A
37	Ultraviolet (UV) radiation environmental disinfection device	A medical ultraviolet air purifier is a device intended for medical purposes in hospital/clinic to destroy bacteria in the air by exposure to ultraviolet radiation.	B
38	Ultraviolet (UV) radiation chamber disinfection device.	An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous medical device surfaces by dose-controlled UV irradiation.	C
39	Body waste receptacle.	A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.	A
40	Vacuum-powered body fluid suction apparatus.	A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids.	B
41	Washers for body waste receptacles.	A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan.	A
42	Sterilization wrap.	It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	B
43	Ethylene oxide gas sterilizer.	Intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical devices.	C
44	Dry-heat sterilizer.	A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical devices by means of dry heat.	C
45	Steam sterilizer.	A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical devices by means of pressurized steam.	C
46	Liquid chemical sterilants/high level disinfectants.	A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use.	C
47	Hand-carried stretcher.	A hand-carried stretcher is a device intended to carry patient as an assistance for injury or disability.	A

48	Manual Wheeled stretcher.	A manual wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability.	A
49	Motorised Wheeled stretcher.	A motorised wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability with a motorised mechanism.	B
50	Liquid crystal vein locator.	Inteded to indicate the location of a vein by revealing variations in the surface temperature of the skin.	A
51	Medical washer.	Intended for general medical purposes to clean and dry medical devices, which later undergo sterilization or disinfection before use on patient.	B
52	Medical washer-disinfector.	A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.	B
53	Hydrogen Peroxide Gas Plasma Sterilization System	Intended for sterilization/disinfection of both metal and nonmetal/polymer based medical devices.	C
54	Blood bank centrifuge	Intended to separate blood components of a suspension by application of centrifugal force.	A
55	Environmental chamber for storage of platelet concentrate	A refrigerated environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range	B
56	Blood storage refrigerator	Thses are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.	B
57	Heat-sealing device	A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.	A