

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

NOTICE

File No. 29/Misc./03/2020-DC (199)

Date: 13 SEP 2021


Subject: Classification of medical device pertaining to Operation Theatre 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, 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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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 Operation Theatre

S. No.	Device name	Intended Use	Risk Class
1	Distractor/Retractor s	A surgical device used to separate connected surfaces, and to retain their positions to allow a surgical operation to be performed.	A
2	Suction system portable, Electrical/Pneumatic	A device that generates negative pressure used for such treatment as the aspiration of liquid or granular substances.	A
3	Suction system operated by vacuum	A device used for such treatment as the aspiration of liquid or granular substances by using negative pressure supplied by the hospital's medical gas supply system at bed side for using on patient.	A
4	Operation table system	A complete surgical table system intended change the patient's position and enable attaching various table accessories that aid in surgery.	A
5	General-purpose diagnosis/treatment table	A table for general diagnosis and procedures in examination room to aid in patient examination.	A
6	Surgical light system	An illuminator device intended to providing optimal light and colour rendering to aid in performing surgery.	A
7a	Non-sterile Hemostatic clip applier	A surgical device designed to apply a hemostatic clip for ligation of a blood vessel.	A
7b	Sterile Hemostatic clip applier	A surgical device designed to apply a hemostatic clip for ligation of a blood vessel.	B
8	Hemostatic knife	The blade intended to transmits heat directly to body tissues to achieve hemostasis.	B
9a	Non-sterile Scalpel	An instrument used to sever and separate body tissues during surgery.	A
9b	Sterile Scalpel	An instrument used to sever and separate body tissues during surgery.	B
10	Scalpel blade	A blade intended to be attached to the handle of scalpel.	B
11a	Non-sterile Surgical forceps	A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues.	A
11b	Sterile Surgical forceps	A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues.	B
12	General-purpose electrosurgical unit	A unit used to resect/ablate the tissue or to coagulate the incision/wound site with high-frequency waves.	C
13	Long-term use enterostomy feeding tube	A hollow device to be placed surgically in the stomach, duodenum or jejunum to provide enteral nutrition. It is for long-term use.	C
14	Warming high-flow infusion pump	A device to be used for heating and rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries.	C
15	High-flow blood transfusion pump	A device to be used for rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries.	C

16a	Non-sterile Staple remover	A metal or plastic surgical instrument used to remove staples from a surgical wound or incision that no longer requires stapling to stay closed.	A
16b	Sterile Staple remover	A metal or plastic surgical instrument used to remove staples from a surgical wound or incision that no longer requires stapling to stay closed.	B
17a	Non-sterile Surgical punch	A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc.	A
17b	Sterile Surgical punch	A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc.	B
18a	Non-sterile Surgical file	A manually operated, hand-held surgical instrument with a series of bumps or teeth on its surface that is used to smooth out, grind off, or sever tissues.	A
18b	Sterile Surgical file	A manually operated, hand-held surgical instrument with a series of bumps or teeth on its surface that is used to smooth out, grind off, or sever tissues.	B
19a	Non-sterile Blood vessel surgical stripper	A surgical instrument used for complete or partial vascular resection.	A
19b	Sterile Blood vessel surgical stripper	A surgical instrument used for complete or partial vascular resection.	B
20a	Non-sterile Surgical probe	The device is used to explore sinuses, fistulae, and other cavities and wounds.	A
20b	Sterile Surgical probe	The device is used to explore sinuses, fistulae, and other cavities and wounds.	B
21	Multiparameter monitor with critical parameters	A unit that collects monitoring parameters (include an electrocardiogram (ECG), blood pressure, body temperature, cardiac output, and respiratory gases; in addition, other critical parameters (supporting detection of arrhythmia or apnea; and in the case of anesthesia, determination of dose levels of a relaxant or local anaesthesia) using an embedded function kit, module, or other devices to display data, by bed or by patient.	C
22	Surgical robot unit	An operation support device used in open surgery or endoscopic surgery that performs treatment of tissues including suturing, detaching and severing, and installing a prosthesis.	B
23	Motorized diagnostic imaging view box	A device equipped with an electric mechanical or software controlled motor that retains, retrieves, and projects light for direct observation of medical images taken using a variety of methods such as X-ray, magnetic resonance (MR), CT, and ultrasound, and recorded in radiographic film.	A
24	General-purpose manually-operated operation table	A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Manual or hydraulic operation.	A
25	Powered general-purpose operation table	A completely mobile surgical table (general-purpose) that has been improved to make it useable for almost all parts of the body that require surgery. Electrically line or battery operated.	A
26	Operation table system	A system that consists of several components that form a complete surgical table system. It is used to replace tabletops, change the patient's position, and transfer the patient to and from the operating room. Usually, it consists of columns, a removable tabletop, remote controller for the trolley, and a trolley.	A