

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

Notice

File No. 29/Misc./03/2020-DC (147)

Date: 26 JUL 2021

Subject: Classification of Medical Device pertaining to Dermatological & Plastic Surgery 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 is hereby classify 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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Classification of Medical Devices Pertaining to Dermatological & Plastic Surgery

Sr. No.	Medical Device Name	Intended Use	Risk Class
1	Organ bag.	An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.	B
2	Surgical camera and accessories.	A surgical camera and accessories is a device intended to be used to record operative procedures.	A
3	Implantable ligating clip	An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.	C
4	Laser surgical instrument for use in general and plastic surgery and in dermatology.	A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.	C
5	Low energy ultrasound wound cleaner	A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds.	B
6	Non-powdered surgeon's glove.	A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination	A
7	Surgical drape and drape accessories	A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial and other contamination.	B
8	Suture retention device	A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient	B

9	Ultraviolet lamp for dermatologic disorders.	An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photo activate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.	B
10	Wound auto fluorescence imaging device	A wound auto fluorescence imaging device is a tool to view auto fluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.	B
11	Battery-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a battery-driven device	B
12	Carbon dioxide laser	A gas laser that is used in surgical procedures. It utilizes carbon dioxide as the substrate. It is widely used in several clinical fields (e.g., gynecology, neuroscience, dermatology).	C
13	Colonoscope, General & Plastic Surgery	Colonoscopes are used for the removal of foreign bodies, excision of tumors or colorectal polyps (polypectomy), and control of hemorrhage. Routine colonoscopy is important in diagnosing intestinal cancer	B
14	Copper vapour laser	A gas laser used in surgical procedures, etc. It utilizes copper vapor as the substrate. It is used in dermatology, etc. for treatment of cutaneous vascular lesions (e.g., port-wine stains, telangiectasia).	C
15	Cryosurgical unit and accessories	A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.	B
16	Dermal dilator	A device to be temporarily implanted subcutaneously to dilate the surrounding skin. Usually, a balloon is implanted subcutaneously where solutions including saline solution are infused.	B
17	Dermatome	A surgical knife used to harvest the skin for grafting. Either manual or electric-powered.	A

18	Dermatome skin approximation tape	A tape that comes in various sizes with adhesive on both sides. It is attached onto a skin graft knife to collect a skin graft tissue. This device is for single-use.	A
19	Drape adhesive.	A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.	A
20	Electrically-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard soft tissues, or soft tissues.	B
21	Electrosurgical cutting and coagulation device and	Electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.	C
22	Electrosurgical device for over-the-counter aesthetic use	An electrosurgical device for over-the-counter aesthetic use is a device using radiofrequency energy to produce localized heating within tissues for non-invasive aesthetic use.	B
23	Esophagoscope, General & Plastic Surgery	An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section changes its shape corresponding to the shape of the body cavity. The device is inserted through the oral cavity.	B
24	Eye pad.	An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.	A
25	Gas-powered dermatome	A gas pressure-operated surgical device used to cut a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	B
26	Gas-powered surgical saw	A saw has a handpiece with an attachment that generates vibration or reciprocal movements. It adopts either a micro or macro design. Rechargeable batteries are used. Usually, compressed air or compressed nitrogen is used.	B

27	Gas-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a gas-driven device.	B
28	Gastroscope, General & Plastic Surgery	A gastroscope is a flexible tube that has a small light and a video camera attached to the end of it. The tube can be used to take tissue samples by inserting instruments such as small pincers.	B
29	General electrosurgical unit	A device accompanied by accessories that cuts/coagulates tissues with a high-frequency current or with the electricity/heat of the heating element. The device is used by a physician to confirm that an incision or coagulation is made as intended, macroscopically or microscopically.	C
30	Hemostatic knife	A surgical severing instrument that is similar to a scalpel, excluding the fact that its blade is designed to be heated with an electric current. The blade transmits heat directly to body tissues to achieve hemostasis. The instrument uses thermal energy for the purpose and requires no grounding pad.	B
31	Hydrophilic wound dressing.	A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon).	A
32	Implantable staple	An implantable staple is a staple-like device intended to connect internal tissues to aid healing.	C
33	Internal tissue marker.	An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.	A
34	Irrigating wound retractor device.	An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound	B

35	Laparoscope, General & Plastic Surgery	"These electrodes are intended for use in minimally invasive surgical procedures where monopolar electrosurgical cutting and coagulation are desired	B
36	Laparoscopy Tray	Laparoscopy Tray is intended for single-use to enable a suitable trained health care professional to perform an laparoscopic procedure.	A
37	Liposuction catheter	A rigid tube inserted into the subcutaneous layer transdermally for removal of fatty deposits. Aspiration is performed with an appropriate unit. This device is for single-use.	B
38	Manual operating table and accessories and manual operating chair and accessories	A manual operating table and accessories and a manual operating chair and accessories are non-powered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.	A
39	Manually-operated dermatome	A hand-held surgical device used to sever a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	A
40	Occlusive wound dressing.	An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device.	A
41	Plastic surgery osteotome	A surgical, chisel-like, instrument designed to cut and/or shape small bones and/or cartilage during plastic surgery. It is hand-held by the surgeon who will typically use a surgical mallet or hammer to manually impart an impacting force to the proximal end of the instrument.	A
42	Powered corneal trephine	An electric cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft.	B
43	Powered dermatome	An electric surgical device used for removal of the fragment of damaged skin or for thinly slicing the skin of a donor for skin graft. A dedicated blade should be used for these purposes.	B

44	Powered suction pump.	A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter	B
45	Removable skin clip	A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable	B
46	Removable skin staple	A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.	B
47	Reusable dermatome blade	A blade that comes in various sizes, attached to the skin graft knife, and is used to harvest the skin graft. This device is reusable after sterilization. Usually, the blade point should be sharpened periodically.	A
48	Single-use dermatome blade	A blade, available in various sizes, attached to a dermatome for collection of skin grafts. The device is intended for single-use.	B
49	Skin marker	A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.	A
50	Skin Stapler	Skin Stapler is intended to be applied to close lacerations on the outer layer of the dermis.	B
51	Soft tissue trephine	A cylindrical or coronary saw used to resect discs of tissues other than bones. It comes in various sizes and configurations according to the size and hardness of the tissue to be resected.	B
52	Surgical apparel.	Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate	A

53	Surgical guillotine	A cutter that consists of a metal frame. The cutter slides through the frame. It comes in various configurations and sizes according to the type of tissue to be severed. Various cranks or shaft driver mechanisms generate the power.	A
54	Surgical lamp	Identification. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.	A
55	Surgical microscope and accessories.	A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.	A