

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

Notice

09 SEP 2022

File No. 29/Misc./03/2022-DC (228)

Date:

Subject: Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures 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 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

Classification of non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures placed at Appendix A subjected to the followings:

1. General intended use given these devices is for guidance. 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

F. No. 29/Misc./03/2022-DC (228)
Government of India
Directorate General of Health Services
Ministry of Health & Family Welfare
Central Drugs Standard Control Organisation
(Medical Devices Division)

FDA Bhawan, Kotla Road,
New Delhi- 110002

Notice

Classification of Medical Devices pertaining to non-sterile, non-powered, hand-held or hand-manipulated Surgical Instruments for general use intended to be used in various general surgical procedures

'Non-Sterile and Invasive Surgical Instruments' are commonly intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be used after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

S. No.	Name of the Medical Devices	Intended Use	Risk Classification
1	Cutting and Dissecting Surgical instruments	These are transient use invasive surgical instruments, usually have sharp edges or tips to cut through skin, tissue, and suture material. Intended to cut and dissect tissue to explore irregular growths and to remove dangerous or damaged tissue. Also used for cutting sutures.	A
2	Clamping and Occluding Surgical instruments	These are transient use invasive surgical instruments, intended for use in many surgical procedures for compressing blood vessels or hollow organs. In order to prevent their contents from leaking or control bleeding or Occlude. They are designed straight, curved or angled, or ratcheted and have a variety of inner jaw patterns.	A

3	Retracting and Exposing Surgical instruments	These are transient use invasive surgical instruments, intended to hold back, or retract organs and tissue, or other article to have access to the operative area during surgical procedure. They spread open the skin, ribs and other tissues; and are also used separate the edges of a surgical incision.	A
4	Grasping and Holding Surgical instruments	These transient use invasive surgical instruments are intended to grasp and hold tissue or blood vessels that may be in the way during a surgical procedure. Designed serrated or non-serrated at the tip.	A

Note for clarification:

1. “transient use” means a device intended for continuous use for less than sixty minutes.
2. “invasive device” means a device which, in whole or part, penetrates inside the body, either through a body orifice or through the surface of the body.



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