

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

NOTICE

File No. 29/Misc./03/2020-DC (178)

Date: 13 SEP 2021

Subject: Classification of medical device pertaining to Pain Management 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 (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 is hereby classify 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,
CDSCO Website

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Classification of Medical Devices Pertaining to Pain Management

Sr. No	Medical Device Name	Intended Use	Risk Class
1	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.	A
2	Acupuncture electrical stimulation system	An assembly of devices used to apply electrical stimuli to acupuncture sites.	B
3	Acupuncture kit	A collection of instruments and supplies used to perform acupuncture procedures.	B
4	Acupuncture point detector	An electronic probe used to precisely locate an acupuncture point on a patient's body.	B
5	Analgesic spinal cord electrical stimulation system	An assembly of devices that applies an electrical stimulus to all or part of the spinal cord to relieve pain (analgesia).	C
6	Bite relief pad	A thin, plastic, horseshoe-like wafer that is placed between the upper and lower sets of teeth and bitten down on, or chewed, to help relieve pain or discomfort after orthodontic treatment.	A
7	Cryogenic analgesia unit	A device designed to provide analgesia by applying extremely low temperatures to body tissues. It is used for postoperative and chronic intractable pain relief.	C
8	Ear microsystem needle	An instrument used in auriculotherapy to apply continuous pressure to stimulate meridian points.	A
9	Electric pad localized-body heating system	An assembly of devices designed for the transcutaneous application of heat to a localized body site to relieve musculoskeletal pain.	B
10	Endothermic cold therapy pack	A device intended to be applied with pressure to the body surface to provide cold therapy to help reduce fever, pain, and inflammation associated with joint/muscle/tissue injury and/or minor burns.	B
11	Foot bath	A device designed to be filled with water to provide therapeutic heat treatment specifically to the feet. This device is intended to relieve foot pain as well as headaches, coughs, and other cold symptoms.	A
12	Heat therapy gel	A non-sterile gelatinous compound in a container that is dispensed for application to the body surface to provide a warming effect for underlying tissues. It is intended to reduce/relieve pain, muscle tension, and to increase local circulation.(Not in direct contact with tissue)	A
13	Ice bag	Intended to alleviate pain and/or promote healing in minor injuries of the body or for application around the neck or limbs.	A

14	Ice collar	Intended to alleviate pain and/or promote healing in minor injuries of the neck, throat, and/or head and to alleviate a sore throat.	A
15	Implantable intrathecal infusion pump	A device designed to be implanted in a patient for the storing and subarachnoid (intrathecal) administration of narcotics/drugs to manage intractable pain and muscle spasms of malignant or non-malignant origin.	D
16	Implantable lumbar neuromuscular electrical stimulation system	The system is designed to deliver episodic electrical stimulation to nerves that innervate lumbar muscles to elicit contraction for the treatment of chronic low back pain (CLBP).	D
17	Inflatable hot/cold therapy pack/electric pump	A assembly of devices intended for localized thermal and compression therapy to facilitate the treatment of a variety of adverse conditions resulting from musculoskeletal injury.	B
18	Inhalational analgesia unit	A device primarily designed to administer analgesic gases to the patient, or produce analgesic vapours for inhalation.	B
19	Intervertebral disc prolapse therapy pack	A device intended to be applied to the skin overlying an affected area of the spine (cervical or lumbar) to reduce pain associated with a prolapsed (herniated) intervertebral disc.	B
20	Intubation teeth protector	A device designed to fit over the upper and lower sets of teeth to protect them from damage during endotracheal (ET) tube intubation procedures.	A
21	Inversion table	A fixed framework with a tilting table platform designed to support the body of a patient and provide traction for the back muscles and spine by allowing the patient manually invert their entire body in a supine position (feet up and head down), thereby assist patients eliminate/alleviate back pain.	A
22	Massage table/couch	A table designed for various kinds of complementary therapy.	A
23	Neurophysiologic monitoring system	An assembly of devices designed to monitor and provide electrical stimuli to spinal nerves or other neural pathways during intraoperative surgery or intensive care, typically to reduce the incidence of accidental injury during instrumented spine surgery, or to diagnose acute dysfunction in corticospinal conduction.	C
24	Pain-relief phototherapy skin patch	A skin patch designed to reflect the naturally emitted infrared energy back into the body, with a reduced range of wavelength, intended to provide comfort and localized temporary relief of body aches and pains by phototherapeutic stimulation of strategic points on the skin.	B
25	Sitz bath	A tub filled with water, that is heated by its heating elements and circulated by its agitators, intended for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.	A
26	Sitz bath chair	A device designed to be sat upon by a patient in a powered sitz bath for external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.	A