

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

NOTICE

File No. 29/Misc./03/2020-DC (160)

Date: 04 AUG 2022

Subject: Classification of medical device pertaining to Rehabilitation 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.

Updated 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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Classification of Medical Devices Pertaining to Rehabilitation

S.No	Name of the Medical Device	Intended use	Classification India as per First Schedule part-1 MDR 2017
1	Acupressure calf band	Intended to wear around the calf to apply pressure to an acupressure point to relieve low back pain, including sciatica and piriformis syndrome. A Non powered belt like device.	ClassA
2	Arthritis TENS system	Intended to be used as adjunctive therapy in reducing the level of pain and stiffness associated with rheumatoid arthritis or osteoarthritis by electrically stimulating peripheral nerves across the skin (transcutaneous).	ClassB
3	Back/leg/chest dynamometer, electronic	Powered device intended to assess neuromuscular function by measuring the force or power exerted by the back, chest, and/or leg muscles during flexion.	ClassB
4	Back/leg/chest dynamometer, mechanical	Non powered device intended to assess neuromuscular function by measuring the force or power exerted by the back, chest, and/or leg muscles during flexion.	ClassA
5	Balance-training tongue electrical stimulation system	Intended to provide biofeedback for training of balance by sensing body movements and subsequently producing signals which are translated into electrical stimuli applied to the tongue, enabling a patient to correlate electrotactile stimulation with their head and body position during exercise sessions.	ClassB
6	Bed/chair electric massager	Intended to provide therapeutic massage to the occupant of a bed or chair for the treatment of body aches and pains.	ClassB
7	Bicycle ergometer	Intended to be used to provide a quantitative measurement of the rate at which work (energy) is performed by a muscle or group of muscles under controlled conditions.	ClassA

8	Bladder-emptying vibratory stimulator	Intended to initiate urination and facilitate complete bladder emptying through application of small mechanical vibrations to the lower abdomen to promote urethral sphincter relaxation.	ClassB
9	Blue/red/infrared phototherapy lamp	Intended to emit blue light, red light, and infrared radiation (heating effect) for phototherapy treatment of mild skin disorders (e.g., mild acne), superficial skin wounds, and musculoskeletal symptoms (e.g., pain, spasm, stiffness).	ClassA
10	Circulating-fluid thermal therapy system	Intended to be used to pump heated and/or cooled fluid (e.g., water) through externally applied packs for localized hot and/or cold therapy to help treat a variety of adverse conditions resulting from musculoskeletal injury (e.g., pain, swelling, inflammation).	ClassB
11	Cold compression therapy cervical spine collar	Intended to facilitate, through cooling and compression, the treatment of a variety of conditions resulting from injury/surgery to the neck region (e.g., inflammation, stiffness, whiplash).	ClassA
12	Cold/cool therapy gel	intended for localized topical skin application to provide a cooling effect for underlying muscles/joints to reduce pain and swelling.	ClassA
13	Cold-air therapy unit	Intended to reduce localized pain/inflammation, and/or to reduce thermal skin damage by applying cold stream of air during dermatological laser treatments.	ClassB
14	Core-body mechanical weight exerciser	Intended to enable a patient with a lumbar spine injury to perform controlled extension, contraction, and/or twisting movements of the lumbar/thoracic spine back region and the abdomen, for testing and rehabilitation.	ClassA
15	Deep-tissue electromagnetic stimulation system	Intended to apply an electromagnetic (EM) field to body tissues to: 1) treat musculoskeletal disorders (e.g., osteoarthritis, osteoporosis); 2) treat body pain (musculoskeletal, postsurgical); and/or 3) help facilitate soft and hard tissue wound/injury healing, with no production of a therapeutic deep heat.	ClassB
16	Electromechanical orthopaedic extracorporeal shock wave therapy system	Intended to provide electromechanical orthopaedic extracorporeal shock wave therapy (OEST) to treat musculoskeletal disorders.	ClassC

17	Electronic goniometer/kinesiology sensor	Intended to evaluate a patient's range of motion/movement of individual joints/limbs/spine; it is used in a clinical setting typically before/after a medical/surgical intervention, or to assess degree of physical fitness.	ClassB
18	Exothermic heat therapy pack	Intended to be applied to the body surface, sometimes with pressure, to provide heat therapy to reduce muscle spasms and cramps and/or for joint and muscle stiffness and pain.	ClassA
19	Foot sensorimotor therapy mechanical neurostimulator	Intended to provide non-invasive peripheral neurostimulation to the feet for improving somatosensory integration, typically for reducing motor impairments and balance disturbances in patients with neurological or neurodegenerative disorders (e.g., Parkinson's disease).	ClassC
20	Gait analysis system	Intended to be used to study walking or running patterns.	ClassA
21	Hand dynamometer/pinch meter, electronic	Electronic device intended to assess neuromuscular function by measuring the force or power exerted by the muscles of the hand/forearm to squeeze/pinch an object.	ClassB
22	Hand dynamometer/pinch meter, mechanical	Mechanical device intended to assess neuromuscular function by measuring the force or power exerted by the muscles of the hand/forearm to squeeze/pinch an object.	ClassA
23	Hydrotherapy treadmill	Powered device intended for use in partially immersed in water, e.g., in a hydrotherapy tank, to provide additional resistance to the treadmill walking exercise without increasing the impact and/or stress on the patient's joints.	ClassA
24	Interferential electrical stimulation system	Intended to stimulate peripheral nerves through the transcutaneous application of two currents of slightly different frequencies that cross-over/interfere, producing a beating frequency at the treatment point.	ClassC
25	Manual goniometer	Non powered device intended to be used in a clinical setting to measure the range of motion of the limb of a patient by measuring the angle of movement achieved at the joint.	ClassA

26	Medium-wave diathermy treatment system	Intended to produce a therapeutic deep heat within specific volumes of the body through the transcutaneous transmission of electromagnetic (EM) energy in the radio-frequency (RF) bands of 0.5 MHz to 1 MHz	ClassB
27	Microwave diathermy treatment system	Intended to produce a therapeutic heat 1 to 2 cm below the skin within specific volumes of the body through the transcutaneous transmission of high frequency electromagnetic (EM) energy, typically 2,450 megahertz (MHz) [microwave], to promote tissue healing and pain relief.	ClassB
28	Musculoskeletal infrared phototherapy unit,	Intended to provide a source of infrared (IR) heat for localized treatment of musculoskeletal pain/injury (e.g., muscle pain, sports injury, rheumatism) and to improve blood circulation in the treated areas to facilitate healing.	ClassB
29	Musculoskeletal intense therapeutic ultrasound system	Intended to produce and deliver intense therapeutic ultrasound (ITU) waves through the skin to create ablative lesions in subcutaneous soft tissues (e.g., muscles, tendons).	ClassC
30	Musculoskeletal/physical therapy laser	Intended to provide noninvasive laser therapy [e.g., infrared phototherapy, low-level laser therapy (LLLT)] for localized treatment of musculoskeletal conditions (e.g., muscle pain, sports injury, disorders of the joints and soft/connective tissues), improving blood circulation in the treated areas to facilitate healing, or for non-needle acupuncture.	ClassC
31	Parallel bar exerciser,	Intended to assist users in maintaining good walking posture, particularly a person with a disability, a paraplegic, or a patient who has suffered a stroke and is learning to walk.	ClassA
32	Physical therapy massager	Electrically powered device intended to provide therapeutic massage to a larger area than hand-held massaging devices.	ClassB
33	Physical therapy paraffin wax bath	Intended to be filled with liquid paraffin wax for physical therapy.	ClassB
34	Physical therapy steam bath	Intended to apply hot steam as a physical therapy to a patient.	ClassB
35	Pulsed signal therapy system	Intended to regenerate damaged cartilage, particularly by stimulating the production of collagen types that are present in healthy cartilage.	ClassC

36	Short-wave diathermy treatment system	Intended to provide a therapeutic deep heat within specific volumes of the body through the transcutaneous transmission of electromagnetic (EM) energy in the radio-frequency (RF) bands of 13 MHz to 27.12 MHz	ClassC
37	Telemetric diagnostic spirometer	It is a Battery powered portable device Intended to measure several or all respiratory-gas volume and flow parameters needed to evaluate basic pulmonary function [e.g., vital capacity (VC), peak expiratory flow (PEF), forced expiratory volume (FEV), and forced expiratory flow (FEF)], and to transmit the pulmonary function data via a communication device to a healthcare professional(s) at a remote server.	ClassB
38	Therapeutic nuclear magnetic resonance system	Intended to influence cellular metabolism using nuclear magnetic resonance (NMR) for the treatment of degenerate and pathological changes to the movement/support profiles of a patient's body, in particular diseased skeletal joints, bones, and surrounding muscle tissue (e.g., cervical and lumbar spine, shoulders, elbows, hands, hips, knees, feet).	ClassC
39	Silicone Prosthetic Ear	A silicone prosthetic ear which adheres to the skin using safe, biocompatible glue is a reconstructive option for patients born with microtia and other birth differences such as Treacher Collins or Goldenhar syndrome; as well as those who have suffered traumatic injury or undergone cancer resection surgery.	Class A
40	Silicone Prosthetic Nose	Silicone prosthetic nose is used to restore normal contour and improve function for patients who have experienced partial or total loss of their nose to traumatic injury, disease or due to surgical removal of the nose (rhinectomy).	Class A
41	External assembled lower limb prosthesis	An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following:	Class A

		Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.	
42	External limb prosthesis socket liner	The prosthetic liner acts as an interface that goes between a person's skin and his or her prosthetic. In short, it's a barrier – one that is applied to the skin before the prosthesis to protect the wearer's skin while enhancing comfort and maintaining a more consistent fit.	Class A
43	Finger/thumb prosthesis	An artificial substitute for a missing finger or thumb.	Class A
44	Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components.	A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.	Class B
45	Powered lower extremity exoskeleton	A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.	Class B
46	Truncal Orthosis	A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of	Class A

		truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.	
47	Prosthesis External Arm	External prosthesis for upper limb distal to shoulder joint. The device is intended to be used by patients with upper limb loss or deficiency. Prosthesis may include limb components, socket, frame, covering and accessories to enable functional use of the device.	Class A
48	Congenital hip dislocation abduction splint	A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).	Class A
49	Denis Brown splint	A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.	Class A
50	Arm sling	An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.	Class A
51	Crutches	Crutches helps to transfer load from the legs to the upper body. This is useful for people who cannot use their legs to fully support the weight of their body, due to temporary or permanent disabilities.	Class A
52	Power Knee	The Power Knee is a motor-powered microprocessor knee. It provides active assistance while walking on level-ground, climbing and descending ramps or stairs and when standing up. Power Knee enables amputees to maintain and regain mobility and participate in the daily activities.	Class B

53	Abdominal Support	It holds abdominal muscles together to relieve pain. Increase circulation at your surgical site to promote healing and decrease swelling. Make physical activity more comfortable.	Class A
54	Myoelectric forequarter-amputation prosthesis	The complete control system is to be used exclusively for external prosthetic fitting of the upper limbs.	Class A
55	Stocking, medical support	Limb support shaped as a stocking unit that is worn on the upper or lower extremity to support, correct, prevent deformity, or to align body structures for functional improvement.	Class A
56	Back Support/Brace	A back brace prevents unnecessary movements that further damage the back. This helps align your spine and strengthen your back muscles. Patients back can heal and back pain will decrease.	Class A
57	Prosthetic and orthotic accessory	A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.	Class A
58	External limb orthotic component	An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.	Class A
59	External limb prosthetic component	An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis.	Class A

		Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.	
60	Prosthesis, external, arm, component, hand, external powered, myopotential	A controller for prosthetic terminal devices that enables grip and mode switching using passive RFID tags.	Class A



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