

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: 26 JUL 2021

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 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 hereby classifies 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 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.	A
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).	B
3	Back pulldown exerciser	Intended to strengthen the muscles of the back (especially the latissimus dorsi) through a repetitive pulldown motion performed with the arms against the force of a weight.	A
4	Back row exerciser	intended to strengthen the muscles of the back through a repetitive rowing motion (as in rowing a boat with oars) performed with the arms against the force of a weight.	A
5	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.	B
6	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.	A
7	Balance ball exerciser	Intended to be used as an unstable surface on which to perform exercise to improve balance and posture.	A

8	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.	B
9	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.	B
10	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.	A
11	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.	B
12	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).	A
13	Body elastic exerciser	Intended to primarily strengthen several or all of the major muscle groups of the body (i.e., in the arms, legs, chest, back, and/or abdomen) through repetitive body motion against elastic resistance.	A
14	Body flywheel exerciser	Intended to strengthen several of the major muscle groups of the body (i.e., in the arms, legs, chest, back) through repetitive body motion against a flywheel.	A
15	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).	B
16	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).	A

17	Cold/cool therapy gel	intended for localized topical skin application to provide a cooling effect for underlying muscles/joints to reduce pain and swelling.	A
18	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.	B
19	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.	A
20	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.	B
21	Electric massager	Intended for respiratory therapy or physiotherapy (e.g., help reduce muscular tension, arthritic pain or joint mobility) in the home and/or healthcare facility.	B
22	Electromechanical orthopaedic extracorporeal shock wave therapy system	Intended to provide electromechanical orthopaedic extracorporeal shock wave therapy (OEST) to treat musculoskeletal disorders.	C
23	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.	B
24	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.	A
25	Finger/hand exerciser	intended primarily to strengthen the muscles of the fingers and hands through repetitive finger/hand motion against resistance from elasticity or density.	A

26	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).	C
27	Gait analysis system	Intended to be used to study walking or running patterns.	A
28	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.	B
29	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.	A
30	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.	A
31	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.	C
32	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.	A
33	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	B
34	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.	B

35	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.	B
36	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).	C
37	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.	C
38	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.	A
39	Physical therapy massager	Electrically powered device intended to provide therapeutic massage to a larger area than hand-held massaging devices.	B
40	Physical therapy paraffin wax bath	Intended to be filled with liquid paraffin wax for physical therapy.	B
41	Physical therapy steam bath	Intended to apply hot steam as a physical therapy to a patient.	B
42	Pulsed signal therapy system	Intended to regenerate damaged cartilage, particularly by stimulating the production of collagen types that are present in healthy cartilage.	C
43	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	C
44	Standard treadmill, mechanical	Intended to facilitate in-place walking, jogging, or running to promote muscle redevelopment, to restore motion to joints, and to promote weight loss and cardiovascular fitness.	A

45	Standard treadmill, powered	Electrically powered unit intended to facilitate in-place walking, jogging, or running to promote muscle redevelopment, to restore motion to joints, and to promote weight loss and cardiovascular fitness.	A
46	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.	B
47	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).	C
48	Wall bars	A device that is permanently fixed to the wall intended for training and rehabilitation to regain and/or improve body movement and balance and/or for strengthening the limbs and the trunk of the body.	A