

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

Notice

File No. 29/Misc./03/2020-DC (202)

Date: **26 JUL 2021**

Subject: Classification of Medical Device pertaining to Physical support 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 Physical Support

S.No	Name of the Medical Device	Intended use	Classification India as per First Schedule part-1 MDR 2017
1	Ankle continuous passive motion exerciser	Electrical device intended to continuously move the ankle joint (e.g., flexion, inversion/eversion) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joint.	B
2	Ankle/foot orthosis	Intended to encompass the ankle joint, or the ankle and foot, to support, align, prevent, or correct orthopaedic deformities/injuries or to improve function of the ankle and/or foot; it may also be intended to offload and redistribute foot pressures that affect pedal circulation to improve blood flow and help heal diabetic foot ulcers or postsurgical wounds.	A
3	Balance board	Intended to train patient with difficulties in balance (e.g., a paraplegic or a stroke victim) walks for balance training.	A
4	Bed traction frame	Intended to treat patients with fractures and other orthopaedic disorders (e.g., of the lower or cervical spine, hip).	A
5	Body arch traction table	Intended to support the body of a patient and provide traction for the back muscles and spine by flexing the patient into a reverse supine body arch.	A
6	Canalith repositioning procedure chair, manual	Intended to treat balance disorders [e.g., benign paroxysmal positional vertigo (BPPV), canalithiasis] caused by displaced canaliths (otoconia) in the inner ear of the patient	A

7	Cervical spine collar	Intended to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains (often to treat whiplash resulting from an automobile accident).	A
8	Cervical spine immobilization head ring	Intended to be fixed to the skull of a patient at brow level using pointed, steel, threaded bolts (typically four) that are adjusted to penetrate the outer bone of the skull.	D
9	Cervicothoracic spine orthosis	Intended to support or immobilize deformities, fractures, sprains, or strains of the cervicothoracic spine.	A
10	Cervicothoracolumbosacral spine orthosis	Intended to encompass the cervicothoracolumbosacral spine region of the neck and trunk.	A
11	Chest-oscillation airway secretion clearing system	Intended to rapidly inflate and deflate against the chest wall of the patient for promoting airway clearance by creating high frequency chest wall oscillation (HFCWO), resulting in the mobilization of bronchial secretions.	B
12	Collar and cuff arm sling material	Fabric and form composite material intended to immobilize forearm, elbow, humerus or shoulder injuries.	A
13	Cranial orthosis	Intended to be worn on the head of an infant with an abnormal head shape (e.g., due to plagiocephaly, brachycephaly, scaphocephaly), or after craniosynostosis repair surgery, to apply pressure to the cranium and improve cranial symmetry/shape during growth over a period of months.	A
14	Elbow orthosis	Intended to encompass the elbow joint to support, align, prevent, or correct deformities/injuries or to improve function of the elbow.	A
15	Finger orthosis	Intended to encompass the whole or part of the finger to support, align, prevent, or correct deformities/injuries or to improve function of the finger.	A
16	Flotation therapy bed, adult	Intended to minimize pressure points on a patient's body by providing contact with as much of the body surface as possible, typically through a mattress that contains a large volume of constantly moving media, e.g., water, air, or mud that lifts the patient to simulate a floating effect.	B

17	Flotation therapy bed, neonatal	Intended to minimize pressure points on neonatal patient's body by providing contact with as much of the body surface as possible, typically through a mattress that contains a large volume of constantly moving media, e.g., water, air, or mud that lifts the patient to simulate a floating effect.	B
18	Foot orthosis	Intended to encompass the whole or part of the foot, or designed as a plantar insert, and intended to provide rigid or semi-rigid correction of the foot for persons with orthopaedic deformities/injuries of the feet	A
19	Hand orthosis	Intended to encompass the whole or part of the hand to support, align, prevent, or correct deformities/injuries or to improve function of the hand.	A
20	Hand/finger splint	Intended to immobilize an injured hand to protect injuries to, e.g., the digits, metacarpals, and wrist during the healing process.	A
21	Hand/wrist continuous passive motion exerciser	A mains electricity (AC-powered) device Intended to continuously move the metacarpal/interphalangeal joints (e.g., flexion and extension) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joints.	B
22	Hip/knee continuous passive motion exerciser	A mains electricity (AC-powered) device Intended to provide continuous passive motion (CPM) exercise therapy for the hip and/or knee, typically following joint surgery/trauma to promote healing; some types may also operate with patient assistance under controlled active motion (CAM).	B
23	Horizontal non-powered traction system	Non powered device intended to be attached to a table for the application of constant horizontal traction forces to the cervical or lumbar vertebrae by means of attached harnesses whilst the patient typically lies in a supine position on the table during treatment.	A
24	Incentive spirometer	Intended to be used in respiratory therapy to encourage and motivate deep-breathing manoeuvres, typically for the postsurgical treatment and prevention of atelectasis (lung collapse) and to help facilitate airway opening and clearing.	A

25	Intermittent traction system	It is an AC powered electronic device. Intended to apply and relieve pre-set traction forces from a motor through harnesses typically attached to the cervical or lumbar vertebrae.	B
26	Kinetic bed	Intend to enable continuous change of the patient's lying position, e.g., it can tilt the entire bed mattress support system (this includes the mattress, the framework that supports the mattress, and the bedding) lengthways, sideways or to a near vertical tilt.	A
27	Knee immobilizer	Intended to temporarily render the knee immovable, either preoperatively or following injury or arthroscopy.	A
28	Neuro-controlled ambulation exoskeleton	Intended to assist a patient with a walking disability (neurogenic, muscular, or osseous in origin) regain lost motor function by transmission of the patient's residual nerve function, via cutaneous electrodes, to the device motor assembly.	C
29	Orthopaedic bed	Intended to provide support for skeletal traction to stabilize fracture sites.	A
30	Paediatric dorsiflexion slant board	Intended to be used in the treatment of various medical conditions (e.g., congenital, neurological, post-traumatic) in paediatrics, where tendon tightness and muscle contracture affect the ability to dorsiflex the foot, possibly leading to an abnormal gait	A
31	Parapodium walking frame	Intended to encompass and provide support for the body of a patient who is unable to stand unassisted to help them move (walk) by changing their centre of gravity (COG).	A
32	Physical therapy massager	Electrically powered device intended to provide therapeutic massage to a larger area than hand-held massaging devices.	B
33	Shoulder continuous passive motion exerciser	It is a mains electricity (AC-powered) device Intended to continuously move the shoulder joint (e.g., flexion, rotation, adduction/abduction) without patient assistance during continuous passive motion (CPM) exercise therapy usually following surgery or trauma to the joint.	B
34	Shoulder immobilizer	Intended to temporarily immobilize or limit abduction of the shoulder joint to support healing of an injury or a surgical wound.	A

35	Swivel-walker	Intended to encompass and provide support for the body of a patient who is unable to stand unassisted, to help them move (walk) by rocking sideways (shifting their weight from side-to-side with a shoulder movement) which makes the footplate of the device swivel so that it “walks” forward.	A
36	Toe separator	Intended to space the toes of the foot to relieve pain, pressure/friction between toes, and/or to facilitate realignment of the toes to a natural position.	A
37	Traction table, line-powered	Intended to support a patient and to provide traction for the back muscles and spine (e.g., lumbar, cervical) by a motorized mechanical manipulation of the spine.	B
38	Wrist immobilizer	Intended to temporarily render the wrist immovable as therapy for non-displaced fractures, strains, sprains, and muscle injuries of the wrist.	A