

MEDICAL DEVICE GUIDANCE DOCUMENT

CLASSIFICATION OF REHABILITATION, PHYSIOTHERAPY AND SPEECH THERAPY DEVICE



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Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

- a) Medical Device Act 2012 (Act 737);
- b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission; and
- “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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CLASSIFICATION OF REHABILITATION, PHYSIOTHERAPY AND SPEECH THERAPY DEVICE

1 Introduction

The definition of medical device is legally binding in the Medical Device Act 2012 (Act 737) and it determines the scope of regulatory control of the product. This definition differentiates medical devices and not medical device based on clear indication on mode of action for the product been used for rehabilitation, physiotherapy and speech therapy.

It is the responsibility of the manufacturer to demonstrate that its product is safe and perform as its intended use/ purpose based on essential safety and performance criteria for the medical device.

This document is intended to provide guidance to manufacturers and authorised representatives on the classification of rehabilitation, physiotherapy and speech therapy products.

2 Scope

This guidance document provides the classification of a list of products used for rehabilitation, physiotherapy and speech therapy by determining whether they are medical devices or non-medical devices based on their intended purpose as claimed by the manufacturer.

3 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 disability

An umbrella term for impairments, limitations of activity and restrictions on participation resulting from the interaction between people with health conditions and the environmental barriers they encounter.

[SOURCE: MS 2752 Prosthetic and orthotic devices - Code of practice]

3.2 disorder

An illness that disrupts normal physical or mental functions.

A set of problems, which result in causing significant difficulty, distress, impairment and/or suffering in a person's daily life. physical or mental conditions that disturb the regular or normal functions of everyday activities and day to day life. They can take up a lot of time and complicate the normal functioning of an individual.

3.3 rehabilitation

A set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment.

[SOURCE: MS 2752 Prosthetic and orthotic devices - Code of practice]

3.4 therapy

Restoring and compensating for the loss of functioning, and preventing or slowing deterioration in functioning in every area of a person's life.

[SOURCE: WHO]

3.5 physiotherapy

Physiotherapy (sometimes referred to as physical therapy) services to individuals and populations to develop, maintain and restore maximum movement and functional ability throughout the lifespan, including in circumstances where movement and function are threatened by ageing, injury, pain, disease, disorders, conditions or environmental factors. Functional movement is central to being healthy.

[SOURCE: MS 2752 Prosthetic and orthotic devices - Code of practice]

3.6 intended use/ purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.7 manufacturer

As defined in Section 2 of Act 737.

3.8 medical device

As defined in Section 2 of Act 737.

4 Classification of rehabilitation, physiotherapy or speech therapy device

4.1 General requirements as medical device

The rehabilitation, physiotherapy or speech therapy instrument, apparatus, implement, machine, appliance, material or other similar or related article that fits the definition of medical device.

Some products that are used in rehabilitation, physiotherapy and speech therapy may not be classified as medical devices.

The list of products for rehabilitation, physiotherapy or speech therapy that are classified as medical device are as listed in Annex A.

Annex A (normative)

Products classified as medical devices

PRODUCT NAME	DESCRIPTION / INTENDED PURPOSE/ INDICATION
Ambulation training	
Parallel bars (floor mounted parallel bar with motorized / wooden platform)	Constructed for patients undergoing physical therapy for their lower body, these bars help through simulated walking to get them back on their feet.
Training stairs (bariatric stairs, wheelchair stairs, training stool, stairs with platforms, convertible stairs)	Intended for patient therapy or rehabilitation. Specifically intended as a tool to help patient move during physical therapy. Essential equipment for rehabilitation of lower extremities can be found here. Space-saving options, convertible configurations, and adjustable parallel bars are crucial for the facility.
Wheelchair training	Essential equipment for rehabilitation of lower extremities for wheelchair patient.
Band / tube	
Exercise band and tubing	For rehabilitation, physical therapy.
Boards/pads	
Foot and ankle rehabilitation boards	Adjustable Range-Of-Motion (ROM) and weight training to maximize lower body rehabilitation.
Miscellaneous balance boards/pads (wobble board, rocker board, slideboard)	Can be used for balance, coordination, ankle and knee strengthening and rehabilitation, ankle range-of-motion and flexibility, core stability, improved posture, and proprioceptive training. Only to use for rehabilitation, physiotherapy/physical therapy.
Multi-axial platform system (including professional board, weight rod, 5-ballset)	Adjustable ROM (range-of-motion) and weight training to maximize lower body rehabilitation.
Quad boards	The quad board provides support by forcing the proper amount of knee (or arm) flexion. The board can be used on a treatment table or floor. Board folds flat when not in use. Each section can be adjusted independently to match exact femoral and tibial lengths. Adjustability of this quad board allows for the knee to be fixed to any degree.
Upper Body Range-of-Motion (ROM) Exercises (Double Curved Shoulder Arc, Climbing Board, Horizontal Ring Tree, Incline Board, Vertical Ring Tree, Semi-Circular Pegboard, Pipe Tree)	Increase upper extremity ROM, strength, coordination and endurance, or improve cognitive and visual skills. For people with neurological disorders, burns and orthopedic problems.

PRODUCT NAME	DESCRIPTION / INTENDED PURPOSE/ INDICATION
Cognitive / vestibular / sensory / motor therapy	
Modular fine & gross motor therapy activities (spiral maze, twisting bar, latch & knob, adjustable finger ladder, rotationknob)	improve fine and gross motor skills, activities mimic items used on a daily basis, for those with functional limitations of hands, fingers or wrists, improve movement, ROM and quality of life by reinforcing independent day-to-day activities. Ideal for OT, hand therapy and those recovering from stroke or traumatic brain injury.
Cognitive / vestibular / sensory / motor therapy	
Vestibular- sensory integration and movement (suspension system, swing set)	Intended for vestibular and sensory integration therapy. Sensory therapy mostly can improve difficulties associated with autism.
Massagers (electric massager, percussion massager, rotary massager, point relief massager) massager (chiropractic)	Chiropractic: chiropractic thrust adjustment device for spine and extremities. To be used together for patient treatment using chiropractic method. For chiropractic and/or rehabilitation purposes only.
Mats	
Exercise mats	A professional exercise mats. Intended for therapeutic workouts, fitness workouts involving tumbling, rehab, yoga, Pilates, floor exercises, stretching, mobility and stability to prevent from injury. NOTE: Not classified as medical device if the general use is for exercise.
Measurement	
Goniometer, inclinometer, scoliometer	Posture evaluation instruments provide accurate and repeatable measurements. Use to measure thoracic and lumbar ROM, lateral and forward flexion and extension of the spine. Can detect scoliosis and abnormal anteroposterior curve. It also measures the unstable lumbosacral, cervical and thoracic curves.
Miscellaneous	
Transfer / gait belts	Gait belts are a back-saving device for caregivers. Help to lift and transfer as well as provide a secure grasp on patients with limited mobility and balance deficiencies.
Pediatric tools	
Pediatric gait trainers (crickets, walker, kaye, crutches, luminator, safety roller & stroller)	Walkers and gait trainers help children to walk thereby increasing independence, self-esteem and social interaction.
Pediatric mobility product (crawler, crawltrainer)	Designed for children who have difficulty being able to crawl, creep or walk often benefit from equipment that helps them move and explore their environment. It will reinforce weight-bearing, shifting and reaching.
Pediatric positioning: seating system (positioning seat, roll chair, positioning system)	Designed for children with mild to severe physical involvement to facilitate the body posture. Seating systems can help position the child on the floor as well as the table to participate in day to day situations with their peers. It may be used in combination with wedges, rolls or blocks to help position the child comfortably. Positioning wedges, rolls and blocks provide stability and support for individuals lacking some degree of body control. Use devices when sitting or lying in prone or supine positions.

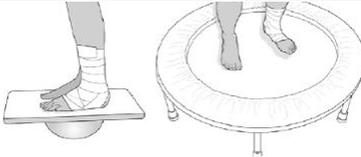
PRODUCT NAME	DESCRIPTION / INTENDED PURPOSE/ INDICATION
Pediatric positioning: sensory & vestibular stimulation (plastic ball stool/trainer, plastic ball chair, wobble ball, inflatable exercise balls, saddle rolls, tortoise shell, crawl mat/box, barrel roll)	Inflatables improve balance, coordination, flexibility and strength. Used by therapists for vestibular movement and equilibrium therapy, by fitness professionals for stretching and strength programs, as seats, and even in birthing classes.. Use during vestibular therapy stimulation, training, general balance exercise, aids in developing muscles, coordination & balance and grossing motor skills.
Pediatric positioning: swing frames for vestibular training and play therapy, swing seat, swing system	Adaptive swings provide safety and support for children with children with special needs and allow socialization at the same time It accommodates therapy modules for vestibular, neurodevelopmental, and sensory integration therapy. Swing seats are ideal for improving vestibular function as well as developing visual, spatial, perception and postural control abilities.
Speech therapy	
Cognitive, speech & sensory motor management (cognitive performance test)	To determine baseline function and serial changes in adult clients with cognitive disorder.
Cognitive, speech & sensory motor management (dexterity test)	Use to obtain a detailed cognitive profile to effectively plan for intervention management and maintenance using the non-injured hand, followed by a timed test of each hand. Quick and simple-to-administer dexterity test.
Cognitive, speech & sensory motor management (monofilaments sensoryevaluator)	Designed for testing loss of protective sensation due to peripheral neuropathy, diabetic foot, nerve compression injuries.
Cognitive, speech & sensory motor management (sensory stimulation activities kit)	A sensory stimulation and basic cognitive rehabilitation program including auditory, visual, olfactory, gustatory and tactile stimuli.
Cognitive, speech & sensory motor management (stereognosis kit)	Use to retest clients and monitor improvement during treatment.
Cognitive, speech & sensory motor management (speech remedy kit)	Designed by speech therapist for use with neurologically impaired developmentally delayed adults, kids for speech therapy session, cognitive group therapy, caregiver training. Focus on improving cognitive skills. For home and clinic use.
Treadmill / body trainer / bike / elliptical	
Body trainer (upper & lower body trainer)	The purpose of total body ergometer is to restore some or all of the patient's physical, sensory, and mental capabilities that were lost due to injury, illness, or disease. Total body ergometer is a treatment or treatments designed to facilitate the process of recovery from injury, illness or disease to as normal a condition as possible.
Rehabilitation treadmill	Intended to be used for patients in any stage of rehabilitation with the assistant of physical therapist and nurses.
Treadmill	Treadmill which specifically intended for therapy or cardiac therapy purposes.

PRODUCT NAME	DESCRIPTION / INTENDED PURPOSE/ INDICATION
Upper range-of-motion (ROM) exerciser (finger / wrist / hand / shoulder)	
Ergonomic hand grip	It is intended for strengthening wrists, hands, finger and forearms from earliest stages of rehabilitation and athletic training.
Exercise putty and putty tools	Can be used in therapy to improve grip strength, dexterity, and hand strengthening through finger, hand and wrist resistive exercises for pediatrics to seniors. Enable users to compliment the work done at the clinic or hospital, allowing strength and mobility progress to continue at home.
Finger weight exerciser	Helps prevent this by isolating both the extensors and flexors, the muscles responsible for opening and closing the fingers. It stays comfortably and securely on your fingers while being used for therapy and rehabilitation.
Flexible hand bar exercise	Flexible hand bar exerciser is a lightweight, portable exerciser designed to strengthen muscles in the hand, wrist and shoulder. Also promotes coordination and increases range-of-motion. Perform oscillation movements for neuromuscular and balance training.
Hand exercise balls	Gel squeeze ball hand exercisers can be used for grip strength, dexterity, mobility, and fine and gross motor skills.
Hand exercise web	Hand therapy exercise web is used in hand therapy for flexion, extension, opposition, and supination exercises.
Hand exercise with band	Designed to develop isolated finger strength, flexibility and coordination, therapy device that isolates the extension of all five fingers and each of the individual finger joints. Also builds hand and forearm strength to aid in the rehabilitation of carpal tunnel, arthritis, stroke, fractures, tendon injuries, nerve lacerations and tennis elbow.
Hand exercisers (hand grip exerciser, hand ball exerciser)	Hand exerciser that helps develops isolated finger strength, flexibility, and coordination for rehabilitation of carpal tunnel, arthritis, stroke, fractures, tendon injury, nerve lacerations, tennis elbow and more.
Pinch finger exerciser	To improve hand and finger strength and coordination. Utilized by patients recovering from hand injuries or individuals with disabilities. They are ideal for a variety of applications, including sports facilities, physical therapy centres, clinics, hospitals, and retirement homes.
Power wheel system (hand wheel, shoulder wheel, wrist wheel)	Enable the repetitive practice of different movement and task including fingers. To improve hand, shoulder and elbow's range-of-motion and strengthen specific hand / shoulder / arm muscle. For rehabilitation purposes.
Upper body range-of-motion (ROM) exercises (double curved shoulder arc, climbing board, horizontal ring tree, incline board, vertical ring tree, semi-circular pegboard, pipe tree)	Increase upper extremity ROM, strength, coordination and endurance, or improve cognitive and visual skills. For people with neurological disorders, burns and orthopaedic problems.

PRODUCT NAME	DESCRIPTION / INTENDED PURPOSE/ INDICATION
Wedges / rolls / balls / disc	
Exercise positioning (wedges, rolls, halfrolls, knee support)	<p>Exercise positioning that can be used under the back, arm, or leg of a patient for comfortable and functional positioning to provide the necessary leverage to promote an exercise regime. Ideal in institutional use in physical therapy departments, home use, special education programs, pre-school programs, physical education classes.</p> <p>NOTE: Not medical device if it is only used for positioning and not for diagnostic or treatment activity.</p>
Foam ball exerciser	Intended for the early stages of hand rehabilitation
Weight	
Wrist and Ankle weights, Adjustable Cuff Weight	<p>Use for progressive therapy or for rehabilitation of a specific injury.</p> <p>NOTE: Not a medical device if it is used for general wellness purposes.</p>

Annex B
(informative)

Examples of medical devices for rehabilitation, physiotherapy and speech therapy

PRODUCT NAME	PICTURES	PRODUCT NAME	PICTURES
Ambulation training		Treadmill / body trainer / bike / elliptical	
Adjustable height and width platform mounted parallel bars		Rehabilitation treadmill	
Band / tube		Upper range-of-motion (ROM) exerciser (finger / wrist / hand / shoulder)	
Exercise band and tubing		Exercise putty and putty tools	
Boards/pads		Upper range-of-motion (ROM) exerciser (finger / wrist / hand / shoulder)	
Foot and ankle rehabilitation boards		Hand exercise web	
Upper range-of-motion (ROM) exerciser (finger / wrist / hand / shoulder)		Wedges / rolls / balls / disc	
Power wheel system (hand wheel, shoulder wheel, wrist wheel)		Exercise positioning (wedges, rolls, half rolls, knee support)	

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