

# Consultation: Products used for and by people with disabilities

## Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018

### COMMENTS:

1. This paper **does not consider** any products that **are not therapeutic goods**, for example, guide dogs, or noise cancelling headphones (does not have *therapeutic use*), etc. **What about dogs that are provided specifically as “therapeutic” dogs. I am not suggesting a change, but it will need to be clarified.**

### 2. Implications of adopting Option 1(a) – exclusion of “assistive technology”

If **Option 1 (a)** is adopted, the current exclusion in Item 9, Schedule 1 of “household and personal aids, or furniture and utensils, for people with disabilities”, would be replaced with a definition describing “assistive technology”.

1. Any item, equipment, software, or products that are used to increase, maintain, or improve different functional capabilities of people with disabilities, irrespective of the risk associated with the product or its complexity or technology, would be excluded from the therapeutic goods regulation by the TGA. **This is the problem with this definition as it would exclude products which are medical devices. Ignoring risk, complexity and technology would place the user at an increased risk. Also, making them *Excluded* products would have the effect of also excluding them from all parts of the Act, in particular, the advertising requirements. Many of the Class I products are associated with diseases such as osteoarthritis and this would place vulnerable consumers at risk. There is already enough advertising around these products which fall outside of the advertising requirements.**
2. Adopting Option 1(a) will continue the existing broad application of the exclusion of products for people with disabilities, irrespective of the risk associated with the product. This reflects an ongoing perception, not necessarily based in fact, that the risks of goods used for people with disabilities is relatively low, regardless their users,

designs and/or technologies. I fully agree and therefore option 1(a) should not be adopted.

3. This may draw some additional medium or higher risk products into the medical device's regulatory framework, where these are currently excluded as "household and personal aids, or furniture and utensils, for people with disabilities". For example, any sponsors who have not included hearing aids (typically a Class IIa medical device) in the ARTG on the basis that they are a "personal aid for people with disabilities" would need to include these products in the ARTG. I believe that the number of devices which would be brought into the ARTG would be minimal. Also, any person/company who has been placing hearing aids on the market without having them on the ARTG, has done so deliberately.

### Proposed action for Option 2

It is proposed that:

**The current** text "household and personal aids, or furniture and utensils, for people with disabilities" in Item 9, Schedule 1 of the Determination **will be replaced with a list of specified products** that are *determined to be excluded* from the therapeutic goods regulation.

The use of a list, although time consuming and not always current, would clarify what is in and what is not. It would also give us the opportunity to use the *Exempt* part of the Act.

### Questions

#### 1. Option 1(a)

- Do you agree that the exclusion in the Determination currently described as "household and personal aids, or furniture and utensils, for people with disabilities" should be replaced with a definition and description of products known as "assistive technology"? *No, this is too broad and does not reflect a large number of sophisticated devices. The devices that need to be regulated are not generally furniture or utensils. Also, there is no difference between where they are used e.g. Household or outside.*

If 'yes', do you have a proposed definition or consideration to be given when preparing the definition? *ISO 9999 is a good start "3.3*

*assistive product*

*any product (including devices, equipment, instruments, technology and software) especially produced or*

*generally available, for preventing, compensating for, monitoring, relieving or neutralizing impairments, activity*

- Do you consider that the real or perceived risks of harm associated with the use of all specified therapeutic goods coming within the definition of assistive technology are insignificant? *I can't say they all will be harmful however many will be.*
- What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)? *The expectations of the above stakeholder are that these types of devices are safe and controlled.*

#### Option 1(b)

- Do you agree rather than excluding all assistive technologies, the exclusion should be limited to only low risk assistance technologies? *Yes, as long as they do not fall into the*

*definition of therapeutic. We will need to find another name as simple assistive technologies by definition should be low risk.*

- If 'yes', do you have a proposed definition or consideration to be given when preparing the definition? *no*
- Do you consider that the real or perceived risks of harm associated with the use of all specified therapeutic goods coming within the definition of low risk assistive technology are insignificant? *yes*
- What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)? *see above*
- What products are excluded under currently arrangements, but would no longer be excluded under the "low risk assistive technology" definition, and so require inclusion in the ARTG? *Sorry I am not sure.*

## **Option 2**

- Do you agree that the definition "household and personal aids, or furniture and utensils, for people with disabilities" should be replaced with a list of specified products determining these products to be excluded goods and of another list in Schedule 2 determining the products to be excluded goods when these products are used, advertised or presented for supply in a particular way?

If 'yes', could you specify which products provided in Appendix A should be excluded (unconditionally or where they are used, advertised or presented

## **GENERAL COMMENTS**

- A review of the recall for Jan 2019 to September 19 of product for people with a disability shows 4 recall 3 of which involved a risk to the user. I also noted that three of the four recalls were "*undertaken prior to notification of the TGA*" this tend to tell you where some of the sponsors are when it comes to understanding their obligations.
- A review of the IRIS system would also show a number of incidents involving of product for people with a disability.
- As stated above, the down grading of many devices to exempt would open the way for advertising to a vulnerable group. Advertising about arthritis is on the restricted representation for a very good reason. This would include not only the internet but social media.
- Some device which fall into the category of products for people with a disability, are of a high classification in some major jurisdictions, namely wheelchairs and possible lower limb components and microprocessor knees (MPK's).
- The concern I have is that devices intended for this part of the market will be vulnerable because of the lack of review on safety, pre-market, post market, problem reporting and advertising.
- My hope is that the TGA is not using this review to abrogate their responsibilities to this group of users. Also, this document does not seam to have been widely disseminated to the Class I sponsors which does not look very transparent. Using just

the organisation listed in the preface of the document, does not mean that it is widely circulated.

- The best way of doing this is to develop a list of what is in and what is out and then reviewing it on a regular basis. Over the years since the original list was developed, the TGA has always found a reason not to update it which ended up in the situation we are in today.

# Appendix A – List of certain products used by or for adults and children with disabilities

Table A – seeking stakeholders feedback and views on regulatory pathways for specified devices used for people with disabilities.

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should be regulated as a medical device under the TG Act.

The 4th column seeks the reasons for the proposed regulatory pathway.

#### Instructions for Table A:

The 1st and 2nd columns in the table provide the product group titles and their descriptions and intended purposes.

The 3rd column has been included to obtain stakeholders' views on whether the specified products should be entered in either Schedule 1 (products to be excluded unconditionally) or Schedule 2 (products to be excluded goods when these products are used, advertised or presented for supply in a particular way), or whether the product

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Communication devices			



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Non-powered communication system	A non-powered communication system is a mechanical device that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of non-powered communications systems include an alphabet board and a page turner.	2	This is a safeguard if any form of therapeutic claim is made.
Powered communication system	A powered communication system is an AC- or battery-powered device that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include: a specialised typewriter, a reading machine, and a video picture and word screen.	2	This is a safeguard if any form of therapeutic claim is made.
Powered environmental control system	A powered environmental control system is an AC- or battery-powered device that is used by a patient to operate an environmental control function. Examples include: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.	2	This is a safeguard if any form of therapeutic claim is made.
Voice synthesiser / digitiser	An assistive device designed to deliver voice output based either in the reproduction of previously-recorded natural speech and/or on an electronic synthesised voice following a pre-established set of pronunciation rules. It typically consists of an electronic unit with a keyboard and screen; the keyboard may include letters, symbols, or both. The device is often customised to meet the user's needs and is mostly used by patients with disabilities that partially or totally impair voice capabilities, including chronic progressive diseases.	2	This is a safeguard if any form of therapeutic claim is made.
Foreign-language assistive training device	A device designed to be used by a person with a disability for voice and speech training when learning a foreign language.	3	Not therapeutic

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Assistive acoustical orientation device	A battery-powered device designed to be used by a person with a visual impairment that electronically produces a sound or a voice message to help them orientate. It is commonly known as a sound beacon.	2	This is a safeguard if any form of therapeutic claim is made. Also, this needs to have some advertising controls.
Training aid, communication, speaking	A technical aid designed to assist a disabled or infirm person in training and developing communication techniques which involve the use of voice and speech, particularly in relation to the production and awareness of sounds. Aids for training spoken language, S-, F- and Sch-indicators and acoustic spectral analysers are included.	2	This is a safeguard if any form of therapeutic claim is made.
<b>Hearing aid</b>			
Hearing aid, air-conduction, receiver-in-canal	A battery-powered acoustic device intended to compensate for impaired hearing by transmitting amplified sound waves to the eardrum through air. It consists of a microphone and an amplifier in a case behind-the-ear (BTE) connected, via a wire, to a receiver (speaker) in the ear canal [receiver-in-canal (RIC)]; this separation reduces acoustic feedback. The microphone receives sound waves and converts them into electrical signals which are increased by the amplifier and sent as sound waves, by the speaker, to the eardrum. The device is used for mild to profound hearing loss; most types are programmable to enable computerised adjustments for a patient's hearing loss and related factors.	2	This is a safeguard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Hearing aid neck induction loop, active	A portable, battery-powered device worn around the neck intended to receive sound from an audio source [e.g., mp3 player] via a wire (e.g., 3.5mm Jack plug) and transfer it via an audio frequency magnetic field to a hearing aid with an induction coil (i.e., bypassing the hearing aids microphone) when it is switched to the "T" or "M" position, in order for the hearing aid user to hear (e.g., music) more clearly. It typically consists of an input cable leading to a small active amplifier with a wire loop worn around the neck.	2	This is a safeguard if any form of therapeutic claim is made.
Hearing aid enhanced audio attachment	A passive device intended to enable a wired audio transmission from a multimedia device (e.g., computer, phone, mp3 player) to a behind-the-ear (BTE) hearing aid, to enhance the sound quality received by the wearer of the hearing aid. Also known as an audioshoe, it consists of a hearing aid attachment which attaches/plugs directly into the hearing aid, making an electrical connection [e.g., direct audio input (DAI)], to receive power from and transmit the signal to the active hearing aid. A wire is used to connect the device to the multimedia device.	2	This is a safeguard if any form of therapeutic claim is made.
Hearing aid remote control	A battery-powered device designed to be operated by the wearer of a hearing aid to enable discreet wireless (remote) adjustments to the hearing aid (e.g., volume and program changes). It is designed to be conveniently portable (e.g., carried in a pocket, handbag, or attached to a key ring).	2	This is a safeguard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
<b>Visual aid</b>			
Visual orientation material	A device used by a person with a disability who has an impaired sense of orientation to supply information on orientation through sight. This is typically used in their surroundings, e.g. at home, work, and in the normal daily life of society.	1	Not therapeutic
Ophthalmic prism reader	An ophthalmic prism reader is a device intended for use by a patient who is in a supine position to change the angle of print to aid reading.	1	Not therapeutic
Low-vision magnifier	A low-vision magnifier is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles.	1	Not therapeutic
Ptosis crutch	A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.	2	This is a safeguard if any form of therapeutic claim is made.
Ophthalmic bar reader	An ophthalmic bar reader is a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device is placed directly onto reading material to magnify print.	1	Not therapeutic
Assistive talking reading material	A digital medium which presents the content of written publications, e.g., books, in spoken form for the user to comprehend. It is particularly used by a person with a disability and/or a vision impairment or other debilitating condition.	1	Not therapeutic

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Closed-circuit television reading system	A closed-circuit television reading system is a device that consists of a lens, video camera, and video monitor that is intended for use by a patient who has subnormal vision to magnify reading material.	1	Not therapeutic
Magnifying spectacles	Magnifying spectacles are devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images.	1	Not therapeutic
Spectacle frame	A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors.	2	This is a safe-guard if any form of therapeutic claim is made.
Prescription spectacle lens	A prescription spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections in accordance with a prescription for the patient. The device may be modified to protect the eyes from bright sunlight (i.e., prescription sunglasses). Prescription sunglass lenses may be reflective, tinted, polarizing, or photosensitised.	2	This is a safe-guard if any form of therapeutic claim is made.
Low-vision telescope	A low-vision telescope is a device that consists of an arrangement of lenses or mirrors intended for use by a patient who has impaired vision to increase the apparent size of objects. This generic type of device includes handheld or spectacle telescopes.	1	Not therapeutic
Electronic vision aid	An electronic vision aid is an AC-powered or battery-powered device that consists of an electronic sensor/transducer intended for use by a patient who has impaired vision or blindness to translate visual images of objects into tactile or auditory signals.	2	This is a safe-guard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Oral electronic vision aid	An oral electronic vision aid is a battery-powered prescription device that contains an electrode stimulation array to generate electrotactile stimulation patterns that are derived from digital object images captured by a camera. It is intended to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as a white cane or a guide dog.	2	This is a safeguard if any form of therapeutic claim is made.
Image intensification vision aid	An image intensification vision aid is a battery-powered device intended for use by a patient who has limited dark adaptation or impaired vision to amplify ambient light.	1	Not therapeutic
Artificial eye	An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.	3	Medical device in a natural orifice
Scleral shell	A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.	3	Medical device
<b>Prosthetic and orthotic devices</b>			
Accessory	A prosthetic and orthotic accessory is a device intended to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include: 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.	3	Medical device

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
External limb orthotic component	An external limb orthotic component is a device intended 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: A brace-setting twister and an external brace stirrup.	3	Medical device
External limb prosthetic component	An external limb prosthetic component is a device that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include: 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.	3	Medical device
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 device 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.	3	Medical device



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Limb orthosis	A limb orthosis (brace) is a device that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.	3	Medical device
Truncal orthosis	A truncal orthosis is a device intended to support or to immobilise fractures, strains, or sprains of the neck or trunk of the body. Examples are: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.	3	Medical device
External assembled lower limb prosthesis	External assembled lower limb prosthesis is a preassembled external artificial limb for the lower extremity. Examples are: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.	3	Medical device
Arm sling	An arm sling is a device intended to immobilise the arm, by means of a fabric band suspended from around the neck.	2	This is a safe-guard if any form of therapeutic claim is made.
Congenital hip dislocation abduction splint	A congenital hip dislocation abduction splint is a device intended to stabilise the hips of a young child with dislocated hips in an abducted position (away from the midline).	3	Medical device
Denis Brown splint	A Denis Brown splint is a device intended to immobilise the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.	3	Medical device

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Powered wheeled stretcher	A powered wheeled stretcher is a battery-powered table with wheels that is intended for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).	3	Medical device
<b>Chairs and tables</b>			
Mechanical chair	A mechanical chair is a manually operated device intended to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.	3	Medical device
Electric positioning chair	An electric positioning chair is a device with a motorised positioning control that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.	3	Medical device
Flotation cushion	A flotation cushion is a device made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.	3	Medical device
Mechanical table	A mechanical table is a device that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.	3	Medical device



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Powered table	A powered table is a device that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.	3	Medical device
<b>Robotic equipment</b>			
Powered lower extremity exoskeleton	A powered lower extremity exoskeleton is a device that is composed of an external, powered, motorised orthosis that is placed over a person's paralysed or weakened limbs, allowing the person to stand, walk, turn, etc.	2	This is a safeguard if any form of therapeutic claim is made. Note: at the moment the majority of the exoskeletons are associated with OH&S.
<b>Walking aid</b>			
Cane	A cane is a device intended to provide minimal weight support while walking. Examples of canes include: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.	2	This is a safeguard if any form of therapeutic claim is made.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Crutch	A crutch is a device intended for use by disabled persons to provide minimal to moderate weight support while walking.	2	This is a safeguard if any form of therapeutic claim is made. However, a recall was conducted this year were the maximum weight was labelled incorrectly.
Cane, crutch, and walker tips and pads	Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.	1	Not medical devices
Mechanical walker	A mechanical walker is a four-legged device with a metal frame intended to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.	2	This is a safeguard if any form of therapeutic claim is made.
<b>Wheelchairs and three or four wheeled vehicles</b>			
Motorised three-wheeled vehicle	A motorised three-wheeled vehicle is a gasoline-fuelled or battery-powered device that is used for outside transportation by disabled persons.	2	This is a safeguard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Mechanical wheelchair	A mechanical wheelchair is a manually operated device with wheels that is intended to provide mobility to persons restricted to a sitting position.	3	Medical device
Powered wheelchair	A powered wheelchair is a battery-operated device with wheels that is intended to provide mobility to persons restricted to a sitting position.	3	Medical device
Special grade wheelchair	A special grade wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.	3	Medical device
Stair-climbing wheelchair	A stair-climbing wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.	3	Medical device
Stand-up wheelchair	A stand-up wheelchair is a device with wheels that is intended to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.	3	Medical device
Wheelchair accessory	A wheelchair accessory is a device that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap.	3	Medical device as the accessory may change the safety of the device. These also could be covered under Custom made devices.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Wheelchair component	A wheelchair component is a device that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.	3	See above
Wheelchair elevator	A permanently mounted wheelchair platform lift is a motorised vertical or inclined platform lift device permanently installed in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by providing a guided platform to move a person from one level to another, with or without a wheelchair.	1	Not a medical device
Wheelchair platform scale	A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended to weigh a person who is confined to a wheelchair.	2	This is a safeguard if any form of therapeutic claim is made.
<b>Therapeutic use –daily activities</b>			
Daily activity assist device	A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended to assist a patient to perform a specific function.	1	Not a medical device
Powered patient transport	A powered patient stairway chair lift is a motorised lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.	1	Not a medical device



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
<b>Therapeutic use – beds</b>			
Air-fluidised bed	An air-fluidised bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.	3	Medical device
Powered flotation therapy bed	A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.	3	Medical device
Manual patient rotation bed	A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.	3	Medical device
Powered patient rotation bed	A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.	3	See above

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
<b>Therapeutic use – bath and steam cabinets</b>			
Moist steam cabinet	A moist steam cabinet is a device that delivers a flow of heated, moisturised air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.	2	This is a safeguard if any form of therapeutic claim is made. The advertising of these products often have unreasonable therapeutic claims.
Non-powered sitz bath	A non-powered sitz bath is a device that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatised tissues of the perianal and perineal areas.	2	See above
<b>Therapeutic use – exercise equipment</b>			
Exercise component	An exercise component is a device that is used in conjunction with other forms of exercise and that is intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.	2	This is a safeguard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Measuring exercise equipment	Measuring exercise equipment consists of manual devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.	2	This is a safeguard if any form of therapeutic claim is made.
Non-measuring exercise equipment	Non-measuring exercise equipment consists of devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.	1	Not medical devices
Powered exercise equipment	Powered exercise equipment consists of powered devices intended to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.	1	Not medical devices
Powered finger exerciser	A powered finger exerciser is a device intended to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.	2	This is a safeguard if any form of therapeutic claim is made.
Powered external limb overload warning device	A powered external limb overload warning device is a device intended to warn a patient of an overload or an underload in the amount of pressure placed on a leg.	2	This is a safeguard if any form of therapeutic claim is made.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
<b>Therapeutic use – massage and pressure equipment</b>			
Powered inflatable tube massager	A powered inflatable tube massager is a powered device intended to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.	1	Not medical device
Therapeutic massager	A therapeutic massager is an electrically powered device intended to relieve minor muscle aches and pains.	2	This is a safe-guard if any form of therapeutic claim is made.
Non-powered lower extremity pressure wrap	A non-powered lower extremity pressure wrap is a device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.	2	This is a safe-guard if any form of therapeutic claim is made.
Pressure-applying device	A pressure-applying device is a device intended to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.	2	This is a safe-guard if any form of therapeutic claim is made.
Powered muscle stimulator	A powered muscle stimulator is an electrically powered device that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.	2	This is a safe-guard if any form of therapeutic claim is made.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Multi-function physical therapy table	A multi-function physical therapy table is a device that consists of a motorised table equipped to provide patients with heat, traction, and muscle relaxation therapy.	3	Medical device
Power traction equipment	Powered traction equipment consists of powered devices intended for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.	3	Medical device
Traction accessory	A traction accessory is a non-powered accessory device intended to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.	3	See above
Therapeutic vibrator	A therapeutic vibrator is an electrically powered device that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.	2	This is a safe-guard if any form of therapeutic claim is made.
<b>Therapeutic use – hot and cold therapy</b>			
Cold pack	A cold pack is a device that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.	2	This is a safe-guard if any form of therapeutic claim is made.
Hot or cold disposable pack	A hot or cold disposable pack is a device that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.	2	This is a safe-guard if any form of therapeutic claim is made.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Water circulating hot or cold pack	A water circulating hot or cold pack is a device that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.	2	This is a safeguard if any form of therapeutic claim is made.
Moist heat pack	A moist heat pack is a device that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.	2	This is a safeguard if any form of therapeutic claim is made.
Powered heating pad	A powered heating pad is an electrical device that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.	2	This is a safeguard if any form of therapeutic claim is made.
<b>Daily living aid</b>			
Personal hygiene aid, toileting, seat, raised, loose	A technical aid designed to assist a disabled or infirm person in attending to their own personal hygiene requirements during a visit to the toilet. It is a raised toilet seat which is placed directly on the toilet bowl, and which is used to increase the height of the sitting position. This raised toilet seat can easily be removed.	1	Not medical device
Patient lifting system toilet seat	A lifting device designed to be used with a patient lifting system to provide support for an incapacitated or disabled patient who is being transferred and lifted into position to use the toilet. It is a toilet seat-like device upon which the person to be lifted sits and is secured to during the lifting process and while using the toilet.	1	Not medical device but there have been some failures.



Therapeutic good	Description	Choose: 1. Exclude unconditionally 1. Exclude when used, advertised or presented in a particular way 2. Regulate as a medical device	Reasons
Stand-up toilet seat	An electrically-powered seat designed to be attached to a standard or assistive toilet and intended to lower a person with a disability to a conventional sitting level for toileting, and to raise them for easy standing after toileting. The device operates through a built-in lifting/lowering mechanism.	1	Not a medical device
Shower head adjustment adaptor	A device designed to be used by a person with a disability to assist them to adjust the position (height and angle) of the shower head when they are taking a shower.	1	Not a medical device
Chair, bath/shower	A device designed to be sat upon by a person who is bathing, showering, or using some washing facility where there is a need to sit. The sitting requirement can be, e.g. because the person is disabled or infirm, or because it is part of medical treatment.	1	Not a medical device
Fixed-rail armrest	A wall and/or floor fixed-rail system designed to provide arm support for a disabled person to facilitate their movement/mobility. It is permanently-fixed to the wall and/or floor at strategic points in a building or in the home.	1	Not a medical device
Eating/drinking aid, cutlery	A technical aid designed to be used by a disabled or infirm person when eating in order to cut food, or on/in/through which food is moved from a container into the person's mouth.	1	Not a medical device

## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	September 2019

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Reference/Publication #