

Sivantos Pty Ltd

Consultation: Products used for and by people with disabilities

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

24/10/2019

Dear TGA,

Thank you for the opportunity to contribute to the consultation **"Products used for and by people with disabilities"** and the proposal for **amendment to the Therapeutic Goods (Excluded Goods) Determination 2018**.

Sivantos designs, develops and manufactures hearing aids and is the world's largest manufacturer supplying one in four hearing aids globally. Sivantos has a long history full of innovative spirit, life-changing technologies and many world's firsts in the hearing aid industry. Formerly Siemens Audiology, Sivantos' origins date back to the year 1878. Currently, Sivantos supplies hearing aids in over 120 countries worldwide.

Sivantos believes **TGA should opt for Option 2** of the review as we feel this will lead to less ambiguity when it comes to registering devices. However, we believe hearing aid(s) and hearing aid accessories **should remain regulated as medical devices by the TGA (i.e. not on the excluded list)**. Hearing aids are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed.

Please find below the answers to the requested questions relevant to Option 2 as well as commentary regarding currently listed devices in Appendix A. Feel free to contact me if you have any questions.

Yours sincerely



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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?

Yes

- If 'yes', could you specify which products provided in Appendix A should be excluded (unconditionally or where they are used, advertised or presented for supply in a particular way), and which should be regulated as medical devices?

Please provide your reasons for the suggestions having regard to the real or perceived risks associated with the use of the specified products.

Please see Appendix A. Please note we believe hearing aid(s) and hearing aid accessories should remain regulated as medical devices by the TGA (i.e. not on the excluded list).

Hearing aids are **prescribed medical devices** and for safe fitting and operation they need to be **professionally selected (prescribed), fitted and programmed**.

Sivantos guidelines is that this is to be done face-to-face

<https://www.signia-pro.com.au/purchasing-distribution-guidelines/>

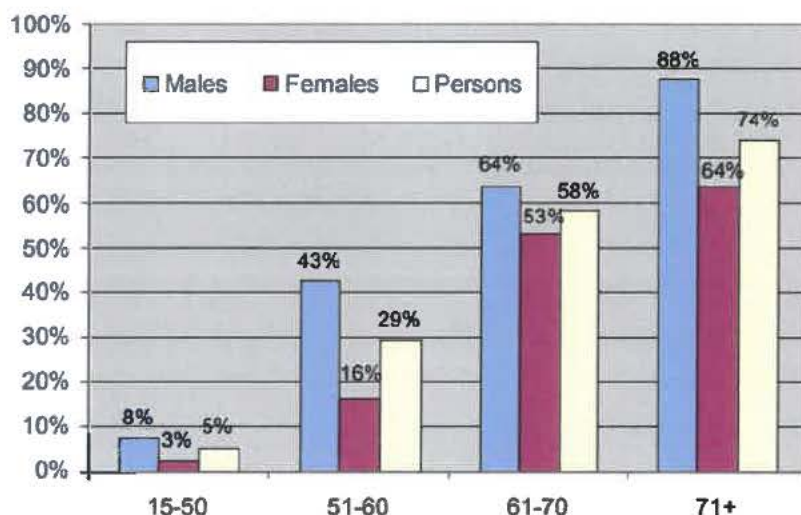
If hearing aids are not regulated under the TG Act we expect that there would be a **significant increase** in adverse incidences or harm to the members of the public.

There are **three major areas** of risk with hearing aid use:

- (a) **Noise-induced hearing loss** – hearing aids need to be precisely programmed to compensate for a patient's specific hearing loss. If hearing aids are set with too much gain and/or output, this can result in over-amplification causing permanent noise-induced hearing loss.
 - (b) **Damage to the ear canal and ear drum** - hearing aids are designed to be worn in discreetly in the patient's ear canal (external auditory meatus). In most cases they are custom-made to the exact shape of the patient's ear. It is very important that they fit comfortably and are positioned at the correct depth. If not, damage can occur to the ear canal and potentially the eardrum (tympanic membrane) and middle ear structures. This is particularly a risk for deeply sitting hearing aid styles like CICs (completely-in-canal) and IIC (invisible-in-canal) models.
 - (c) **Exacerbation of existing medical conditions** – prior to hearing aids being prescribed, clinicians need to determine whether there are any medical contraindications to fitting hearing aids. For example, hearing aids are medically contraindicated when there are outer ear infections.
- Any other relevant matters may also be considered.

In determining the risk to the public, it is important to understand the main user groups and their ability to independently manage these areas of risk (highlighted above). Hearing aids are fitted to vulnerable segments of the public, including young children (paediatric) and the elderly (geriatric). In fact, the elderly makes up most hearing aid wearers. It is estimated that in Australia the average age of a hearing aid wearer is ~78 years.

A significantly number of patients in these groups cannot independently manage these major areas of risk, for example, a baby or an adult with dementia, may not be able to tell their clinician that their hearing aids are set too loud, therefore risking noise-induced hearing loss.



Access Economics, Listen Hear! The economic impact and cost of hearing loss in Australia, (February 2006)

- 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.)?

We believe a list of "*specified products to be excluded goods*" and of another list "*determining the products to be excluded goods when these products are used, advertised or presented for supply in a particular way*", is the correct approach. We feel this will lead to less ambiguity. The lists need to be regularly updated to support new product categories/concepts as they come to market.

As discussed above we believe hearing aid(s) and hearing aid accessories should remain regulated as medical devices by the TGA (i.e. not on the excluded list). Hearing aids are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed.

- What products are excluded under currently arrangements, but would no longer be excluded under the list of specific products, and so require inclusion in the ARTG?

Please see appendix A

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.

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

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

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Communication devices			
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
	Examples of powered communication systems include: a specialised typewriter, a reading machine, and a video picture and word screen.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose:	Reasons
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.	1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	
Hearing aid			
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.	3/ Regulate as a medical device	Hearing aids are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed. If hearing aids are not regulated under the TG Act we expect that there would be a significant increase in adverse incidences or harm to the members of the public.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. 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.	3/ Regulate as a medical device	Accessories in this category work together with hearing aids. Hearing aids and hearing induction loops are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed. If hearing aids are not regulated under the TG Act we expect that there would be a significant increase in adverse incidences or harm to the members of the public.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.	3/ Regulate as a medical device	Accessories in this category work together with hearing aids. Hearing aids and audio attachments are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed. If hearing aids are not regulated under the TG Act we expect that there would be a significant increase in adverse incidences or harm to the members of the public.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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).	3/ Regulate as a medical device	Accessories in this category work together with hearing aids. Hearing aids and hearing aid remote controls are prescribed medical devices and for safe fitting and operation they need to be professionally selected (prescribed), fitted and programmed. If hearing aids are not regulated under the TG Act we expect that there would be a significant increase in adverse incidences or harm to the members of the public.

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Visual aid			
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.		
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.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. 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.		
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.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. 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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Prosthetic and orthotic devices			
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
Arm sling	An arm sling is a device intended to immobilise the arm, by means of a fabric band suspended from around the neck.		
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).		
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.		
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).		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Chairs and tables			
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. 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.		
Robotic equipment			
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.		
Walking aid			
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.		
Crutch	A crutch is a device intended for use by disabled persons to provide minimal to moderate weight support while walking.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
Wheelchairs and three or four wheeled vehicles			
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.		
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.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Therapeutic use –daily activities			
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.		
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.		
Therapeutic use – beds			
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
Therapeutic use – bath and steam cabinets			
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.		
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.		
Therapeutic use – exercise equipment			
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. 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.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
Therapeutic use – massage and pressure equipment			
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.		
Therapeutic massager	A therapeutic massager is an electrically powered device intended to relieve minor muscle aches and pains.		
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.		
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
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.		
Therapeutic use – hot and cold therapy			
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
Daily living aid			
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.		
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.		
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.		

Therapeutic good	Description	Choose: 1. Exclude unconditionally 2. Exclude when used, advertised or presented in a particular way 3. Regulate as a medical device	Reasons
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.		
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.		
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.		
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.		