



Government of Sierra Leone

National Assistive Technology Standards of Sierra Leone

March 2023

Ministry of Health and Sanitation

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Foreword



Incredible work went into developing the Assistive Technology Standards for Sierra Leone, a document which provides standards and specifications for 30 Priority Assistive Technology (AT) Products for Sierra Leone. One of the wishes of the Government of Sierra Leone is to ensure that the country is inclusive for people with disabilities as clearly expressed in the Midterm National Development Plan (MNDP 2019 to 2023). This is also in line with many other frameworks including the Ministry of Health and Sanitation's three key priority areas of Universal Health Coverage (UHC), Sustainable Development Goals (SDGs), and Equity. As stated in the UHC, every individual and community, irrespective of their circumstances, should have timely access to the high-quality health services they need without risking financial hardship. Attainment of the SDGs requires the empowerment of communities to participate in the design, planning, implementation, monitoring and evaluation of interventions that improve their health outcomes. Communities should also receive feedback from respective duty bearers for their affirmative actions. Equity ensures that the needs of all people living in Sierra Leone are addressed in an equitable manner irrespective of one's ethnicity, gender, age, disability, religion, political belief, geographical location, or economic and/or other social conditions. In addition, as Minister of Health and Sanitation, I welcome the AT standards document which seeks to provide guidance and specifications when procuring AT products for Sierra Leone. These standards were developed by a technical team constituted by the MoHS and were adapted from the WHO and UNICEF standards. The report makes a major contribution to addressing gaps related to AT procurement and service provision by the MoHS. It will also go a long way to ensuring equitable access to AT products and services and ultimately improve the quality of life of persons with disabilities.

A handwritten signature in green ink that reads "Austin Demby". The signature is written in a cursive, flowing style.

Dr Austin Demby

Minister, Ministry of Health and Sanitation

Acknowledgements



The National Assistive Technology Standards of Sierra Leone were developed by the Clinton Health Access Initiative under the AT2030 programme's Country Investment Fund. The AT2030 program is funded by UK Aid from the UK government and led by the Global Disability Innovation (GDI) Hub. We want to acknowledge and thank members of the AT standards subgroup and the Technical Working Group for their dedicated effort and technical support. We wish to acknowledge the support of Dr. Santie Sesay (Director of NCDs, Mental Health and Rehabilitation), Mr. Ismaila Kebbie (National Programme Manager for National Rehabilitation Center), Mr. Francis Kabia (Director of Welfare Ministry of Social Welfare), Mr. Jonathan Conteh (Regional Coordinator for National Commission for Persons with Disability), Mr. Santie Kargbo (President of Sierra Leone Union on Disability Issues) for their tireless support in the successful completion of this document.

We also wish to thank all the stakeholders in the disability community and other contributors in Sierra Leone who made the development of the National Assistive Technology Standards of Sierra Leone possible.

This project is part of AT2030, a programme funded by UK Aid and led by the Global Disability Innovation Hub. AT2030 will test 'what works to improve access to AT and will invest £20m to support solutions to scale. With a focus on innovative products, new service models, and global capacity support, the programme will reach 9 million people directly and 6 million more indirectly to enable a lifetime of potential through life-changing assistive technology. More information at AT2030.org.



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Chief Medical Officer (CMO)
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Acronyms

APS	Assistive Product Standards
APL	Assistive Products List
AT	Assistive Technology
CHAI	Clinton Health Access Initiative
CTEV	Congenital talipes equinovarus
DPPI	Directorate of Policy, Planning, and Information
ENT	Ear nose and throat
HRH	Human Resource for Health
IEC	International Electrotechnical Commission
ISO	International Organization of Standardization
MIT	Massachusetts Institute of Technology
NCDs	Non-Communicable diseases
NRC	National Rehabilitation Centre
SLAS	Sierra Leone Autistic Society
SLEDT	Sierra Leone Education Development Trust
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Definition of Terms

Functional requirements: Describe the functional requirements of each product, including the typical user or typical use, specific characteristics of the product and the standard configuration.

General design requirements: Describe general product performance requirements and overall qualities.

Standards: State the standards with which the product must comply, including international standards (e.g., ISO and International Electrotechnical Commission (IEC), and relevant national and regional standards.

Certificate of conformity: Refers to a certificate of conformity – a legal document signed by the supplier to confirm a product conforms to applicable national or international regulations in the country where it is procured or to the procurement specification.

Size and weight: Describe information the supplier should provide about the dimensions of the product in its standard configuration when folded (for storage), and any adjustment range.

Technical information: Describes the minimum information the supplier should provide about how to maintain, repair, or refurbish the product.

Warranty: This specifies the duration and details of the product warranty.

Lifespan: Specifies the expected lifespan in years of the assistive product.

Packaging, labeling, and state of assembly: Describe packaging requirements, including how products should be packaged, the state of assembly, and package labeling.

Accessories and spare parts: List the required accessories and spare parts that should be procured to ensure the assistive product can be maintained and, if necessary, repaired.

1. Introduction

This document was developed to guide the procurement of assistive products in Sierra Leone. It is intended primarily for procurement teams, implementing partners and donors working on providing AT devices for all forms of disabilities. It should be read alongside the Assistive Technology Procurement Guidelines of Sierra Leone and the Assistive Technology Products List of Sierra Leone. Assistive products are any external products, including devices, equipment, instruments and software, especially produced or generally available, the primary purpose of which is to maintain or improve an individual's functioning and independence and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions. Wheelchairs, spectacles and hearing aids are among the many assistive products that enable people with functional difficulties to participate meaningfully in daily life. Without them, people are often excluded and isolated, while the progression of their disease or functional difficulties may be exacerbated. Determining the assistive product and service requirements at the planning stage of a procurement process is essential to its success. These requirements will be expressed in a procurement specification that forms the basis of a tender announcement, which suppliers use to formulate bids and the procurement team uses to evaluate bids received. It is crucial for adequate planning and resourcing, and for selecting the right assistive products, suppliers, and follow-up services.

This document includes 30 assistive product specifications (APL). The assistive products have been chosen from the Assistive Products List of Sierra Leone published in 2021 to guide the country when making decisions related to assistive product procurement and provision. The APL addresses six key areas of functional difficulties, with products to assist mobility, hearing, vision, cognition, communication, and self-care. The APL describes the minimum requirements related to technical performance and function that the products should meet for safe and effective use. Of the 70 products in the Product List of Sierra Leone, the 30 selected for development were chosen because they are commonly and widely used to address the functional needs of the population; they can be procured in bulk; and they can be provided through primary or community health services. The APL is targeted at anyone involved in assistive product planning or procurement and related services. The APL may also be informative for product manufacturers, service providers, users, and user organizations. This document is presented in two sections: product description; and product requirements. Sections 1 and 2 provide an overview of the information described in each section.

SECTION 1: PRODUCT DESCRIPTION	
	This section provides key information about the group of assistive products included in the specification so they can be easily identified.
1.1	Name of product Provides the name of the product, as described in the national assistive product list (if available) or refers to a commonly used product name.
1.2	International Organization of Standardization (ISO) 9999 code If applicable, provides the ISO classification and terminology for the product (or group of products), as described in ISO 9999:2016
1.3	Description and intended use Give a general description of the product and how a person may use the product to address their needs.
1.4	General features Summarize the key characteristics of the product.
1.5	Inclusion Lists the products included in the APS
1.6	Exclusion Lists the products not included in the APS.
1.7	Keywords List important searchable words related to the product(s)
SECTION 2: PRODUCT REQUIREMENTS	
	This section details the requirements for each assistive product included in the specification. Each requirement is mandatory. This means a supplier must ensure the product meets all requirements.
2.1	Functional requirements Describe the functional requirements of each product, including the typical user or typical use (e.g., body function, daily activities, living environment), specific characteristics of the product (in addition to the general features in 1.4), and the standard configuration.
2.2	General design requirements Describe general product performance requirements and overall qualities (e.g., stability, strength, durability, water resistance).
2.3	Standards State the standards with which the product must comply, including international standards (e.g., ISO and International Electrotechnical Commission (IEC), and relevant national and regional standards.
2.4	Certificate of conformity Refers to a certificate of conformity – a legal document signed by the supplier to confirm a product conforms to applicable national or international regulations in the country where it is procured or to the procurement specification.
2.5	Size and weight Describe information the supplier should provide about the dimensions of the product in its standard configuration when folded (for storage), and any adjustment range. Information about adjustment should include the minimum and maximum adjusted dimensions, and the adjustment increments. Typical dimensions include the overall width, height, length, and weight of the assistive product. Wherever necessary, instruction on how to measure the width, height, length, and weight should be provided to the supplier.
2.6	Technical information (for service providers) Describes the minimum information the supplier should provide about how to maintain, repair, or refurbish the product.

2.7	Instructions for use (for users and caregivers) Describe the minimum user instructions the supplier should provide.
2.8	The environment of use Describes the weather and other environmental conditions that the assistive product should be able to withstand. This information typically includes acceptable lower and upper limits for temperature and humidity, and whether the product can be used in rain, snow, or direct sunshine.
2.9	Warranty Specifies the duration and details of the product warranty.
2.10	Lifespan Specifies the expected lifespan in years of the assistive product.
2.11	Packaging, labeling, and state of assembly Describe packaging requirements, including how products should be packaged, the state of assembly, and package labeling.
2.12	Accessories and spare parts List the required accessories and spare parts that should be procured to ensure the assistive product can be maintained and, if necessary, repaired.
2.13	Other product requirements State any additional product requirements not covered in previous subsections.

2. How to use the Standards

This section guides using the document. This guidance should be read alongside the product-specific information in each APL.

2.1 Identifying the product

2.1.1 Product Description

In Section 1.1, the name of the product should refer to the product name as described in the national assistive product list or follow commonly used terminology.

In Section 1.2, the classification ISO 9999:

Assistive Products for Persons with Disability – Classification and Terminology are provided for reference so the product can be easily identified. The extra six digits given in each APL complete the ISO 9999 code for a category of product (e.g. 18 30 15 for portable ramps).

The section on description and intended use should describe the product clearly and what it should be able to do. The general features should give enough detail to identify the product’s function and characteristics, but also be generic and not biased toward a brand or design. A generic specification encourages competition and allows suppliers to offer innovative assistive products that may be new to the market.

2.2 Choosing the right product to meet the user's needs

2.2.1 Product functional and design requirements

A range of products may be included. For example, wheelchairs can be assistant-controlled or self-propelled and come with additional postural support. There are further variations for use in different contexts (e.g., urban, dual-terrain, and rough-terrain wheelchairs). The product range should include options to meet the different functional and environmental needs of a wide group of users. The capacity of local services to provide the product range is an important factor in decision-making.

For each product, the typical user or use is described, including product characteristics and standard configuration requirements. A description of the typical user is helpful when selecting the product range quantities to be procured; however, identification and selection of the best product to meet an individual's needs are part of the service provision process.

A clear description of the typical user is essential (e.g., relevant health conditions, functional difficulties, age, size range). If applicable, the context of typical and intended use should also be described (e.g., indoor or outdoor use, noisy environments).

The characteristics and standard configuration give enough detail to differentiate between products. The description of the product focuses on function and performance without prescribing a specific (hardware and software) design. This encourages suppliers to seek out appropriate product improvements and innovations. The procurement specification should not require specific materials to be used, mechanisms of functioning, size, or weight of the product. Where relevant, however, information that is important to achieve certain quality standards or functions may be required.

The procurement team should adapt each APL to the population and context. For example, maximum weight load and dimensions for mobility and self-care products (e.g., wheelchairs, rollators, showers, and toilet chairs), and frame size for products including low vision/blindness (e.g., spectacle magnifiers, white canes, and hearing aids), should be specified according to the size range of local users.

Design requirements generally apply to all product variations, which need to be safe and durable and work effectively. Additional design requirements to allow for adjustment and customization are useful considerations for certain products.

2.3 Ensuring quality and safety

2.3.1 Standards and certificate of conformity

Standards exist to ensure products are fit for purpose. Products should be tested by accredited test laboratories according to relevant national or international standards. For some national standards, certain technical requirements are adapted from international standards to fit the local context better – for example, by modifying the temperature and humidity ranges to the environment where the products will be used.



A certificate or declaration of conformity is a legal document signed by the supplier that confirms a product conforms to applicable national or international regulations in the country where it is procured. The supplier should be required to provide a certificate that clearly states the product complies with the terms of the procurement specification in accordance with ISO specifications (which should reflect applicable regulations and standards) and state that it is safe and effective for the intended use. The certificate should be signed by an authorized representative of the supplier.


If products do not comply or are not tested according to the relevant standards stated therein, or if they deviate from the procurement specification, the supplier and procurement team should explain.

3. Compilation of assistive product specifications

3.1 Mobility

Crutches	
Name of product	Crutches, axillary/elbow
ISO 9999 code	12 03 06 Elbow crutches 12 03 12 Axilla crutches 12 03 09 Forearm crutches
Description and intended use.	Crutches are walking aids with elbow, underarm or forearm support and a single shaft fitted with a tip (ferrule). A single crutch or pair of crutches is intended for use by children and adults to support balance or weight-bearing through the leg(s).
General Features	A crutch has a straight or offset handle with an ergonomically shaped handgrip and a height-adjustable shaft fitted with a tip.
Inclusion	'Elbow, axilla, and forearm crutches

Exclusion	
'Walking sticks with or without a seat. Multi-tip walking sticks (e.g., tripods, quadripods) Lateral support frames	
Keywords	
'Arthritis crutches, axillary crutches, axilla crutches, elbow crutches, ferrules, forearm crutches, gutter crutches, platform crutches, tips	
Functional requirements	
1. Elbow crutch	
	
Typical users	Short- or long-term use for a child or adult who needs support to balance or bear weight through their legs.
Specific characteristic	Cuff: <ul style="list-style-type: none"> • closed/semi-circle • hinged/fixed attachment • Ergonomically moulded handgrip Shaft: <ul style="list-style-type: none"> • height-adjustable • fitted with tip Height-adjustment mechanism: <ul style="list-style-type: none"> • quick release • single height adjustment (shaft only) • double height adjustment (cuff and shaft)
Requirements for standard configuration	Complete assembly with an appropriate tip for the environment Tips are securely fitted and made from durable rubber. Three to four different sizes to fit children and adults (e.g., child, youth, adult, tall adult) Bariatric range for users over 120 kg
2. Axilla crutch	
	
Typical user	Short-term use for child or adult who needs support to balance or bear weight through their legs.
Specific characteristics	Cushioned underarm support. Ergonomically moulded handgrip Shaft: <ul style="list-style-type: none"> • height-adjustable • fitted with tip Height-adjustment mechanism:

	<ul style="list-style-type: none"> • double height adjustment (handgrip and shaft)
Requirements for standard configuration	<p>Complete assembly with an appropriate tip for the environment</p> <p>Shaft:</p> <ul style="list-style-type: none"> • adjustable height • commonly made from aluminium or wood <p>- Height adjustment of handgrip independent of the shaft (total height) adjustment</p> <p>- Handgrip commonly made from plastic.</p> <p>- Tips securely fitted and made from durable rubber.</p> <p>- Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult).</p> <p>- Bariatric range for users over 120 kg</p>
3. Forearm crutch	
	
Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs and is unable to use standard handgrip due to hand or arm impairment
Specific characteristic	<p>Forearm support:</p> <ul style="list-style-type: none"> • horizontal support • moulded • cushioned • hook-and-loop fastener <p>Handgrip:</p> <ul style="list-style-type: none"> • telescopic handle rotates through 360 ° <p>Shaft:</p> <ul style="list-style-type: none"> • height-adjustable • fitted with tip <p>Height-adjustment mechanism:</p> <ul style="list-style-type: none"> • quick release • single height adjustment (shaft only)
Requirements for standard configuration	<p>- Complete assembly with an appropriate tip for the environment</p> <p>- Tips securely fitted and made from durable rubber</p> <p>- Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult)</p> <p>- Bariatric range for users over 120 kg</p>

Clubfoot braces	
Name of product	Clubfoot braces
Description and intended use.	

Clubfoot braces are used as part of the overall management of infants and children born with congenital talipes equinovarus (CTEV, idiopathic clubfoot). The braces position the child’s feet to maintain a position after the use of a series of plaster casts (serial casts) to correct the foot.

Clubfoot braces are worn almost all the time in infants. Once the child is of walking age, clubfoot braces are generally used overnight until the condition is resolved. Clubfoot braces are used for children with CTEV affecting one or both feet.

General Features

A clubfoot brace is comprised of two boots that attach to a bar. The boots attach to the bar with a clip or screw and hold the feet in abduction (apart), dorsiflexion (up) and external rotation (rotated outward). The main components are the boots and bar. All boots have a heel cup or well-rounded heel counter. Many boots have an inspection hole at the back to check the child’s heel is flat on the bottom of the boot. Boot fastenings may be straps and buckles, hook-and-loop (Velcro) or laces.

Inclusion

Clubfoot braces that hold both feet in a position of abduction, dorsiflexion and external rotation in boots attached to a bar. Use colors to look attractive.

Exclusion

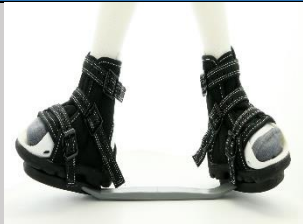
Single-leg clubfoot braces
 Ankle-foot orthoses or preferably in a unilateral CTEV (Clubfoot). The normal foot should be positioned or placed at an angle of 45 degrees and the affected Limb 60 degree abduction to maintain external rotation and dorsiflexion.

Keywords

Clubfoot orthosis, CTEV, foot-abduction brace, foot-abduction orthosis, Ponseti, steam back product (SAB) brace

Functional requirements

1. Clubfoot brace with two boots attached to a bar



Typical user	Infant or child up to age five years who have completed the corrective phase of clubfoot treatment. Should be worn for 24 hours when newly fitted and can be removed at night until the child is 4 years.
Specific characteristics	Fixed bar (width adjustment is an optional feature) Boots that hold feet at shoulder width apart in a position of abduction and dorsiflexion (angle adjustment is an optional feature)
Requirements for standard configuration	Standard configuration should allow for the following adjustments: <ul style="list-style-type: none"> • Length of bar: size range to accommodate infants (0–12 months) and children (1–5 years) (e.g., bar width 12–38 cm) • Bilateral boots: size range to accommodate infants (0–12 months) and children (1–5 years) (e.g., foot bed length 6.4–20.4 cm) • Abduction angle of boot 30–70 ° (allows for unaffected foot) • Dorsiflexion angle of boot 10–15 °

	<ul style="list-style-type: none"> • Smallest assembled size weight range 110–320 g • Largest assembled size weight range 270–650 <p>The shoe should be coloured to attract the child and also comfortable.</p>
<p>General design requirements</p> <p>The clubfoot brace should be designed for ease of use and be strong and durable:</p> <ul style="list-style-type: none"> • easy for the child’s parents or carers to put the boots on and off the child; • Velcro or laces on the boots that are easy to fasten firmly enough to keep the child’s heels down. • within the boots; • easy to clean. <p>The bar should be lightweight but strong enough to maintain the child’s feet in a position of abduction and dorsiflexion (outward and upward angulation respectively). The design should include: a straight medial (inside) border on boot, or medial reinforcement of the boot material to prevent front of child’s foot from angling inwards (forefoot adductus);</p> <ul style="list-style-type: none"> • features to prevent the heel from slipping up inside the boot; • features to prevent or reduce friction on the skin; • large shoelace holes or eyelets if laces are used; • open-toed design because the child’s toes should not be covered in the brace. 	
<p>Standards</p> <p>None</p>	
<p>Certificate of Conformity</p> <p>Should come from the manufacturer</p>	
<p>Technical Information (for service providers)</p> <p>To educate and train the users/caregivers.</p>	
<p>Size and weight</p> <p>The following measurements should be provided:</p> <ul style="list-style-type: none"> • minimum, maximum and increments for adjustable bar or between fixed bar sizes • boot size • overall assembled weight of clubfoot braces 	
<p>Lifespan</p> <p>The product should have a lifespan of at least one year</p>	
<p>Accessories and spare parts</p> <p>The following spare parts should be procured:</p> <ul style="list-style-type: none"> • spare bars • boots • bar and boot connectors • screws and other assembly parts. <p>The following optional accessories may also be procured:</p> <ul style="list-style-type: none"> • padding for bar • strap saddles (to prevent pressure sores on the skin) • shoelace. 	
<p>Other technical requirements</p> <p>Information should be provided in the user manual on how to avoid and check for friction on the skin, how to check and ensure the heel stays down within the boot, and how to put the brace on and take it off.</p>	

Handrails and grab-bars

Name of product

Handrails and grab-bars

ISO 9999 code

18 18 03 Handrails and support rails
 18 18 06 Fixed grab bars and handgrips
 18 18 10 Removable grab rails and handgrips
 18 18 11 Hinged rails and arm supports

Description and intended use.

Handrails or grab-bars are cylindrical rails or bars attached to a wall, floor or other stable structure that a person can hold for support. They are intended for use by children and adults who need support when moving between lying, sitting, or standing, and while standing or moving around in indoor and outdoor environments.

General Features.

A handrail or grab bar is circular in shape, has a continuous construction with no joins or obstruction along the passage of the bar or rail, and has both ends permanently attached to a wall, floor, or ceiling.

Inclusion

Short grab bars and handrails
 Long handrails

Exclusion

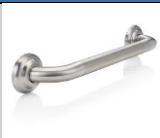
Suction rails

Keywords

Grab-bars, handrails, home modification, support




Functional requirements

1. Wall-mounted straight or angled grab bar



Typical user	Child or adult who needs support when moving between lying, sitting or standing, while standing, or when going up and down steps
Specific characteristics	Both ends are permanently attached to the wall in a horizontal, vertical, or diagonal position
Requirements for standard configuration	<p>Stainless steel, aluminium, brass, wood, plastic, or galvanized tubing with a diameter of 30–50 mm.</p> <p>Clearance from the wall should be approximately 50 mm to ensure sufficient space for finger clearance.</p> <p>Minimum load of 150 kg for a wide platform</p> <p>Fixed or customized length with effective grab length not less than 230 mm</p> <p>Adequate contrast visually with the background wall</p> <p>Satin, power-coated, epoxy-coated, enamel-coated, or polished finishing</p>

2. Floor-to-wall/floor-to-ceiling grab bar

	
Typical user	Child or adult who needs support when moving between lying, sitting or standing, while standing, or when going up and down steps; and where it is not possible to attach the bar to a wall
Specific characteristics	Fixed between wall and floor, or from floor to ceiling
Requirements for standard configuration	Stainless steel, aluminum, brass, wood, plastic, or galvanized tubing with diameter 30–50 mm Clearance from the wall should be approximately 50 mm to ensure sufficient space for finger clearance. Minimum load of 150 kg for a wide platform Fixed or customized length with effective grab length not less than 230 mm Adequate contrast visually with the background wall Satin, power-coated, epoxy-coated, enamel-coated or polished finishing
3. Fold-down/drop-down rail	
	
Typical user	Child or adult who needs support to sit down or to stand up from sitting, or to go up or down a step; and where it is not possible to attach the bar to a wall or where space is limited
Specific characteristics	Has an extra vertical support leg to the floor or looped rail that provides two alternative gripping positions
Requirements for standard configuration	Stainless steel, aluminium, brass, wood, plastic, or galvanized tubing with a diameter of 30–50 mm Clearance from the wall should be approximately 50 mm to ensure sufficient space for finger clearance Minimum load 150 kg for wide platform Fixed or customized length with effective grab length not less than 230 mm Adequate contrast visually with background wall Satin, power-coated, epoxy-coated, enamel-coated, or polished finishing
4. Wall-mounted banister rail	
	
Typical user	Child or adult who needs support to walk up or down stairs or along a corridor
Specific characteristics	Both ends are permanently attached to the wall in a diagonal or horizontal position

Requirements for standard configuration	<p>Stainless steel, aluminium, brass, wood, plastic, or galvanized tubing with a diameter of 30–50 mm</p> <p>Clearance from the wall should be approximately 50 mm to ensure sufficient space for finger clearance.</p> <p>Adequate contrast visually with the background wall</p> <p>Satin, power-coated, epoxy-coated, enamel-coated, or polished finishing</p> <p>Available in standardized lengths of 300 mm, 450 mm, 600 mm and 900 mm</p>
General design requirements	
<p>The handrail or grab bar should be made with strong material, durable and safe for use in the environment of use. The finish should be slip- and rust-resistant. If used in wet areas (e.g. bathrooms), every component of the grab bar or hand rail needs to be waterproof.</p> <p>The option of a color finish should be available for children and adults with visual impairments.</p> <p>The grab bar or handrail should allow the user’s hand to encircle and be in complete contact with the rail when gripping.</p>	
Standards	
<p>ISO 17966:2016 specifies requirements and associated test methods for assistive products for personal hygiene that support users and that are intended by the manufacturer to alleviate or compensate for disability. The work environment and safety aspects for assistants are also included. It specifies safety and performance requirements that apply during normal use and foreseeable misuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and specifies limits on the forces needed for some operations.</p> <p>EN 12182 Assistive Products for Persons with Disability – General Requirements and Test Methods could be considered, and some specifications can be found in ISO 21542 Building Construction Accessibility and Usability of the Built Environment,</p>	
Size and weight	
Information about overall width, length and safe working load of grab-bars and handrails is required	
Environment of use	
The product should withstand a relative humidity range of 15% to 100%.	
Lifespan	
Five years and above	
Accessories and Spare Parts	
Screws	

Portable ramps	
Name of product	Portable ramps
ISO 9999 code	18 30 15 Portable ramps
Description and intended use.	<p>Portable ramps are moveable sloping surfaces that bridge a gap or difference in levels (over a maximum of two steps). They are intended for children and adults who use wheeled mobility devices (e.g. a wheelchair or rollator) to go up and down one or two steps to access a home or other building or to access a vehicle or public transport.</p>
General Features	

A portable ramp is a moveable, flat, non-slip, supporting surface. When used to bridge two levels, it is tilted at an angle with one end higher than the other (inclined plane). Ramp ends are shaped to prevent the ramp from sliding during use and angled for a smooth transition onto and off the ramp. Edges are raised for the safety of the user. A portable ramp may be fitted with carrying handles or supplied with a carrying bag for transportation.

Inclusion
Wide-platform portable ramps
Twin-track portable ramps

Exclusion
Permanent ramps

Keywords
Access ramp, accessibility, bridge, inclined plane surface, non-slip, ramp

Functional requirements

1. Wide-platform portable ramp



Typical user	Child or adult with difficulties going up or down steps or who uses mobility products
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Specific characteristics	One wide platform Can be folded for transportation
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Requirements for standard configuration	Platform made from aluminium, fibreglass or graphite fibre, with non-slip surface made from textured aluminium or rubber Length 100–350 cm Width 72–107 cm Minimum load 270 kg Must have raised edges of height 2–4 cm Fitted with a carrying handle
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2. Twin track portable ramp (two driving tracks)




Typical user	Child or adult who uses a wheelchair, stroller or other three- or four-wheeled mobility product
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Specific characteristics	Two separate tracks Can collapse telescopically for transportation
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Requirements for standard configuration	Platform made from aluminium, fibreglass or graphite fibre, with non-slip surface using deck grip, textured aluminium or rubber Length 100–350 cm Minimum width of each track is 15.5 cm Minimum load 175 kg Must have raised edges of height 2–4 cm Fitted with a carrying handle
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<p>General design requirements</p> <p>The portable ramp should be made with materials that are waterproof, strong, durable and lightweight.</p> <p>Its surface should be non-slip, even in wet conditions. It should be easy to set up and move. It should be safe for repeated use considering the weight of the user, the user's assistive product(s) (e.g. wheelchair) and the carer or assistant (as needed). There should be no risk of trapping fingers when operating the ramp's folding or telescopic mechanism.</p> <p>The portable ramp should be foldable or adjustable for transportation. It should not unfold or move during transport. It should be possible to position and install the ramp without using tools.</p> <p>Transportation length should be a maximum of 150 cm to be easily transported in a standard car.</p>
<p>Standards</p> <p>None</p>
<p>Size and weight</p> <p>Information about the overall width, height, length and weight of portable ramps, including usable surface width and length, and height of side edges, should be required.</p> <p>Dimensions in operating and folded modes should be provided</p>
<p>Environment of use</p> <p>The product should withstand various weather conditions, including rain, dust, snow, ice and sleet, and be appropriate for local temperatures. The product should withstand an ambient temperature range of -30 to +50 °C and a relative humidity range of 15% to 100%.</p>
<p>Lifespan</p> <p>The product should have a lifespan of at least three years</p>
<p>Accessories and spare parts</p> <p>The following accessories should be required:</p> <ul style="list-style-type: none"> • carrying bags.

Therapeutic footwear	
Name of product	Therapeutic footwear
ISO 9999 code	09 03 42 Shoes and boots 09 06 21 Assistive products for heel protection, toe protection or foot protection
Description and intended use.	Therapeutic footwear takes the pressure off problem areas and prevents secondary problems that may lead to amputation. It is intended for use by children and adults with neuropathic or diabetic feet or ankles
General Features	Therapeutic footwear is a pair of shoes or sandals with a removable insole that adds extra depth and cushioning or footwear that allows the use of custom-made insoles. They usually have adjustable closures to ensure a snug-fitting upper to hold the foot in place on the insole preventing restriction and shear forces on the skin; wide and deep toe boxes; a wide heel base; a cuff around the ankle with rolled seams to prevent friction; built-in forefoot rocker; rocker bottom soles; and adjustable straps or shoelaces.
Inclusion	



Prefabricated therapeutic footwear	
Exclusion Custom-made orthopedic shoes and sandals	
Keywords Diabetic footwear, neuropathic footwear, therapeutic footwear	
1. Therapeutic footwear/CTEV shoe	
	
Typical user	Child or adult with diabetic or neuropathic at-risk feet, or foot or ankle deformities, who needs shoes that protect and support foot structure or to take pressure off areas with existing or healed ulcers
Specific characteristics	Prefabricated shoes or sandals with removable insoles to allow insertion of custom-made alternatives to contain deformed or at-risk feet
Requirements for standard configuration	<p>broad deep toe boxes, wide in midfoot, in-flared (forefoot wider on the inside) and out-flared (forefoot wider on the outside), extra depth to accommodate insertion of orthotic or insole</p> <p>Upper design: natural, synthetic materials or materials from renewable sources</p> <p>Types of closure: laces, hook-and-loop fasteners, buckles or combination</p> <p>Heel design: wide heel base, either closed with heel counter or open a width adjustable backstrap</p> <p>Toe design: may be closed (fully covering toes) or open (leaving toes uncovered); in closed-toe design, other features include a vamp/shoe tongue, which provides additional adjustability and protection for the foot</p> <p>Outsole design: built-in forefoot rocker sole or toe-spring to assist in toe-off</p> <p>Sizes: range of child and adult sizes to meet local population needs</p> <p>Extra depth or the removable insole of at least 5 mm thickness</p> <p>Footwear to be supplied complete with fasteners and insoles</p>
<p>General design requirements</p> <p>Therapeutic footwear must fit properly and fasten snugly to prevent movement of the foot. It must provide support and accommodate the shape of the foot and any bony deformities and orthotics or insoles. Footwear should provide comfort and must be easy to put on and take off. Upper materials should be breathable, not allow moisture to be trapped, be fast drying and be available in colours appropriate to the region’s climate and conditions. Shoe uppers should be easily adjustable for people with poor or weak hand function and allow evenly distributed pressure. The cuff or topline around the ankle should be well-fitting and have rolled seams to prevent friction and blistering (, particularly over the Achilles tendon. It can extend over the malleoli (bony projections on either side of the ankle) to add medial and lateral stability if needed.</p>	

<p>Extra-depth/removable insoles allow for the insertion of custom-made orthotics/insoles that provide good heel control to ensure sideways stability.</p> <p>Insoles should redistribute pressure, provide support and cushioning, and be made of materials that are durable, mouldable, and washable.</p> <p>The outer sole and soling materials should be appropriate for the local climate and terrain, be durable and lightweight, provide support and control/traction and be repaired easily with adhesives.</p>
<p>Standards Comfortability and durability.</p>
<p>Certificate of conformity Certificate of conformity must be provided before accepted for use.</p>
<p>Size and weight Weight, size, width and shape of the footwear should be specified</p>
<p>Instructions for Users (users and caregivers) Use Manual</p>
<p>Environment of use The product should be appropriate for the local terrain (e.g. mud, rock), conditions (e.g. rain, snow, ice, sleet), and local temperature and humidity ranges</p>
<p>Lifespan At least two years, provided the product is maintained and used correctly in its intended environment, in line with the product instructions; this period may be adjusted based on the environment, use, and size and weight of the person and existing foot deformity</p>
<p>Packaging, Labelling and State of Assembling Must be properly secured to prevent damage by labelling it appropriately.</p>
<h2>Walking frames</h2>
<p>Name of product Walking frames/walkers</p>
<p>ISO 9999 code 12 06 03 Walking frames</p>
<p>Description and intended use. Walking frames are walking aids with four shafts or with two shafts and two small wheels (castors), which are lifted or pushed by the user. They are intended for use by children and adults to support balance or weightbearing through the legs.</p>
<p>General Features A walking frame has two handgrips and four height-adjustable shafts that end in either four tips (ferrules) or two tips and two wheels. A variety of tips and wheels are available for different products and terrains.</p>
<p>Inclusion Walking frames with four tips Walking frames with two tips and two wheels</p>
<p>Exclusion Rollators</p>

Reciprocal walking frames	
Keywords Walker, a walker with front wheels	
Functional requirements	
1. Walking frame with four tips	
	
Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs
Specific characteristics	<p>Frame:</p> <ul style="list-style-type: none"> • folding or rigid • four height-adjustable shafts <p>Height-adjustment mechanism:</p> <ul style="list-style-type: none"> • telescopic • quick release <p>Handgrips:</p> <ul style="list-style-type: none"> • two moulded grips <p>Tips:</p> <ul style="list-style-type: none"> • four removable or replaceable tips
Requirements for standard configuration	<p>Complete assembly with tips for the user's environment</p> <p>Tips securely fitted, non-slip, and replaceable or interchangeable</p> <p>Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult)</p> <p>Bariatric range for users over 120 kg</p>
2. Walking frame with two tips and two wheels	
	
Typical user	Short- or long-term use for a child or adult who needs support to balance or bear weight through their legs
Specific characteristics	<p>Frame:</p> <ul style="list-style-type: none"> • folding or rigid • four height-adjustable shafts <p>Height-adjustment mechanism:</p> <ul style="list-style-type: none"> • telescopic • quick release <p>Handgrips:</p> <ul style="list-style-type: none"> • two moulded grips <p>Tips:</p> <ul style="list-style-type: none"> • two fitted with wheels and two fitted with tips
Requirements for standard configuration	<p>Complete assembly with tips for user's environment</p> <p>Tips securely fitted, non-slip, and replaceable or interchangeable</p> <p>Wheels do not swivel and only allow forward and backward movement</p> <p>Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult)</p> <p>Bariatric range for users over 120 kg</p>


<p>General design requirements</p> <p>The walking frame should be easy to operate and adjust, be strong and durable, have low deformation risk and high abrasion resistance, be made from lightweight material, and withstand the environment of use. Parts of the walking frame must be replaceable (including wheels).</p>
<p>Standards</p> <p>ISO 11199–1:1999 Walking aids Manipulated by Both Arms – Requirements and Test Methods ISO 24415–1 Tips for assistive products for walking – Requirements and test methods – ISO 24415–2:2011: Tips for assistive products for walking – requirements and test methods – durability of tips of crutches (excludes tips manufactured for special purposes such as ice and snow) EN 1985 Walking aids – General requirements and test methods or equivalent</p>
<p>Size and weight</p> <p>Product dimensions to be provided:</p> <ul style="list-style-type: none"> • overall length • overall width • width between handgrips • overall height and adjustment range(s) • maximum user weight • unit weight • if applicable, dimensions in operating and folding modes
<p>Environment of use</p> <p>The walking frame should withstand heavy use on local terrain and weather conditions (e.g. rain, dust, snow, ice, sleet).</p>
<p>Instructions for Users (users and caregivers)</p> <p>User guide needed.</p>
<p>Packaging, Labelling and State of Assembling</p> <p>Careful packaging to prevent breakages</p>
<p>Accessories and spare parts</p> <p>The following spare parts are required:</p> <ul style="list-style-type: none"> • tips for different environments; • non-swivel wheels for different environments; • handgrips; • height-adjustment mechanisms; • individual components as spare parts.


Walking sticks, tripods and quadripods	
Name of product	Canes/sticks
ISO 9999 code	12 03 03 Walking sticks and canes 12 03 16 multi-tip walking sticks and canes
Description and intended use.	Walking sticks, tripods and quadripods are walking aids with a handgrip and single height-adjustable shaft with one, three or four ends fitted with tips (ferrules). Walking sticks are intended for use by

<p>children and adults to support balance or weightbearing through the leg(s). Tripods or quadripods may be used by children and adults who need additional support.</p>	
<p>General Features A walking stick has a straight or offset handle with an ergonomically shaped handgrip and a height-adjustable shaft. A tripod has three ends and a quadripods has four ends. Each end is fitted with a tip. A variety of tips are available for different products and terrains.</p>	
<p>Inclusion Walking sticks Tripods/quadripods</p>	
<p>Exclusion Forearm, elbow, and axilla crutches</p>	
<p>Keywords Cane, ferrules, tips, walking aids</p>	
<p>Functional requirements</p>	
<p>1. Walking stick</p>	
	
<p>Typical user</p>	<p>Short- or long-term use for child or adult who needs support to balance or bear weight through their leg (s)</p>
<p>Specific characteristics</p>	<p>Handgrip:</p> <ul style="list-style-type: none"> • flat or ergonomically moulded • straight or offset shaft. • height-adjustable folding (optional) • single end fitted with tip • Height-adjustment mechanism: telescopic or quick release
<p>Requirements for standard configuration</p>	<p>Complete assembly with an appropriate tip for the user's environment Tips are securely fitted, non-slip, and replaceable or interchangeable. Three or four different sizes to fit children and adults (e.g., child, youth, adult, tall adult)</p>
<p>2. Tripod/quadripods</p>	
	
<p>Typical user</p>	<p>Short- or long-term use for a child or adult who needs support to balance or bear weight through their leg(s) For use on level terrain only</p>
<p>Specific characteristics</p>	<p>Handgrip:</p> <ul style="list-style-type: none"> • flat or ergonomically moulded. • straight or offset shaft. • height-adjustable folding (optional) • single end fitted with a tip. • Height-adjustment mechanism: telescopic or quick release

Requirements for standard configuration	Complete assembly with appropriate tips for user's environment Tips securely fitted, non-slip, and replaceable or interchangeable Shaft: height-adjustable via clip or push-button; pin should be made from stainless-steel Three or four different sizes to fit children and adults (e.g., child, youth, adult, tall adult)
General design requirements	
The walking stick, tripod or quadripods should be easy to operate, strong and durable, have low deformation risk and high abrasion resistance, and be made from lightweight materials. Parts of the walking stick, tripod or quadripods must be replaceable.	
Standards	
ISO 11334-4:1999 Walking Aids Manipulated by One Arm – Requirements and Test Methods – Part 4: Walking Sticks with Three or More Legs	
ISO 11334-1:2007 Walking Aids Manipulated by One Arm with Three or More Legs	
ISO 24415-1 Tips for Assistive Products for Walking – Requirements and Test Methods – Part 1: Friction of Tips	
ISO 24415-2:2011 Tips for Assistive Products for Walking – Requirements and Test Methods – Part 2: Durability of Tips of Crutches (excludes tips manufactured for special purposes such as ice and snow)	
CNS 15191 (2010)/BS 5181 (1975)/ CPSA 0073 (1996) Static Loading and Junction Strength Test for Wooden Walking Sticks	
CNS 15192 (2010) Adjustable Metal Walking Sticks	
EN 1985 Walking Aids – General Requirements and Test Methods or Equivalent	
Size and weight	
The following information should be provided for all products across all size ranges as specified:	
<ul style="list-style-type: none"> • overall dimensions (length, minimum and maximum handgrip height) • height-adjustment range(s) • maximum user weight • unit weight • dimensions in operating and folded modes (for folding walking sticks) 	
Environment of use	
The walking stick, tripod or quadripods should be appropriate for local terrain and conditions (e.g. sand, mud, rocky ground, rain, snow, ice, sleet).	
Accessories and spare parts	
The following spare parts are required:	
<ul style="list-style-type: none"> • tips for different environmental conditions; • height-adjustment mechanisms; • individual components as spare parts. 	

Wheelchairs, manual	
Name of product	
Wheelchairs, manual assistant-controlled	
Wheelchairs, manual for active use	
Wheelchairs, manual with postural-support devices	
ISO 9999 code	
12 22 03 Bimanual handrim-drive wheelchairs	
12 22 06 Bimanual lever-drive wheelchairs	
12 22 09 Single-side manual drive wheelchairs	

<p>12 22 15 Foot-propelled wheelchairs 12 22 18 Push wheelchairs 12 27 04 Transportation chairs 12 27 07 Prams and buggies 18 09 39 Modular seating systems</p> <p>Other relevant codes: 12 24 Wheelchair accessories 09 07 Assistive products for body stabilization (belts, harnesses) 18 10 Accessories for posture-support wheelchairs</p>	
<p>Description and intended use. Wheelchairs provide wheeled mobility with an appropriate seating system and rely on the user or an assistant to move around. Wheelchairs are intended for children and adults with limited mobility.</p>	
<p>General Features A wheelchair usually has three or four wheels with rear wheel locks or brakes for parking, footrests (foot supports), seat and backrest (back support), armrests (arm supports) and clothing guards. It has push rims or levers for self-propelling and may have push handles for assistant-propelling. It can be foldable or can be dismantled into smaller, separate parts for transportation and storage. A wheelchair can be used with a range of postural-support devices (PSDs) and add-on mobility components for achieving its full function.</p>	
<p>Inclusion Wheelchairs, manual assistant-controlled Wheelchairs, manual for active use Wheelchairs, manual with postural-support devices</p>	
<p>Exclusion Wheelchairs, electrically powered Wheelchairs, standing Trikes (dedicated). Pediatric wheelchairs with adaptations</p>	
<p>Keywords Active wheelchair, adaptive stroller, buggy, manual wheelchair, PSD, postural-support wheelchair, transport/push wheelchair, wheelchair with PSDs, wheelchair with recline, wheelchair with tilt</p>	
<p>Functional requirements</p>	
<p>1. Wheelchairs, manual assistant-controlled</p>	
<p>1.1 Transport wheelchair</p>	
	
<p>Typical user</p>	<p>Child or adult who can sit upright and balanced without additional support For intermittent use for short-duration transportation indoors and outdoors</p>
<p>Specific characteristics</p>	<p>Wheelchair with a folding or rigid frame, four wheels, push-handles, seat and backrest, armrests, footrests, tipping lever, and rear wheels and front castors appropriate for indoor and outdoor use</p>
<p>Requirements for standard configuration</p>	<ul style="list-style-type: none"> • frame with mechanism(s) to fold or dismantle

	<ul style="list-style-type: none"> • fixed seat or seat frame depth • backrest with fixed height, at least at a mid-thoracic height of the user • two flip-up, swing-away or removable footrests with adjustable height • flip-up or removable armrests <p>Rear wheels:</p> <ul style="list-style-type: none"> • diameter e.g. from 305 mm (assistant-propelled) to 660 mm (self-propelled), appropriate for the size of the wheelchair) • rear wheel in line with backrest tubes (back posts) or further to rear <p>Front castors:</p> <ul style="list-style-type: none"> • diameter e.g. 203 mm • width e.g. 25–50 mm <p>Puncture-proof rear tyres and front castors</p> <p>Seat width range: minimum of four sizes</p>
1.2 Adaptive stroller	
	
Typical user	Child or adult who cannot sit safely in an upright posture and requires additional postural support for intermittent use for short-duration transportation indoors and outdoors
Specific characteristics	<p>Wheelchair with folding or rigid frame, three or four wheels, push-handles, seat and backrest with preset tilt, head support and footrests</p> <p>Accepts a range of PSDs</p> <p>Wheels and castors can be in various sizes suitable to the terrain:</p> <ul style="list-style-type: none"> • smaller diameter and narrower width for indoor or urban outdoor terrain • larger diameter and wider width for outdoor peri-urban or rural terrain
Requirements for standard Configuration	<ul style="list-style-type: none"> • frame with mechanism(s) to fold or dismantle • integrated or removable seat and backrest • accepts range of PSDs; seat with preset tilt; variable (dynamic) recline or tilt is optional • head support integrated in or separate from the backrest • single or dual footrests with adjustable height <p>Single or double wheels with puncture-proof tyres</p> <p>PSDs:</p> <ul style="list-style-type: none"> • required accessories – pelvic belt and head support • optional accessories – shoulder harness, foot straps, hip guides, trunk side supports, tray <p>Size range:</p> <ul style="list-style-type: none"> • seat width range – minimum four sizes • seat depth can be extended by at least 50 mm without additional parts

2. Wheelchairs, manual for active use
2.1 Active urban wheelchair



<p>Typical user</p>	<p>child or adult with basic, intermediate or advanced posture support needs Primarily for people who self-propel, but also for people who need assistance For use in urban, indoor and outdoor environments People with advanced mobility skills may also use this wheelchair for short distances on uneven terrain</p>
<p>Specific characteristics</p>	<p>Wheelchair with a folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests, and footrests Overall length and wheelbase are similar to or shorter than transport wheelchairs with large rear wheels. Rear wheels and front castors appropriate for urban indoor and outdoor use</p>
<p>Requirements for standard configuration</p>	<p>Frame:</p> <ul style="list-style-type: none"> • frame with mechanism(s) to fold or dismantle. • push handles can be integrated into the frame, supplied as add-on components, or omitted if not required • backrest or back posts with adjustable height or supplied with a range of back. • posts with fixed height • backrest contouring options, such as tension-adjustable backrest or rigid. • backrest that can be adjusted independently from back posts or with forward. • and backward and angle adjustment, including separate padded cover; can. • be mounted at different heights on back posts; quick-release mechanism to allow folding. • footrests with adjustable height – available in at least two adjustment ranges on all sizes of wheelchairs to accommodate people with shorter and longer legs. • two flip-up, swing-away, or removable footrests on folding frame • optional – armrests and clothing guards with minimal profile <p>Rear wheels:</p> <ul style="list-style-type: none"> • quick-release or removable without tools • optional camber with a maximum of 3 ° (off from vertical) • diameter e.g. 508–660 mm • width e.g. 25–35 mm <p>Front castors:</p> <ul style="list-style-type: none"> • diameter e.g., 127–203 mm

	<ul style="list-style-type: none"> width e.g., 25–50 mm <p>Range of size and width options available Puncture-proof or pneumatic rear tyres and front castors</p> <p>Frame and wheel adjustments:</p> <ul style="list-style-type: none"> rear wheel or seat unit relative to wheelbase can be horizontally adjusted using tools. front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or through a range of different fixed-frame seat heights to optimize fit for foot propelling on folding-frame wheelchairs. <p>Optional for basic-level services but required for postural support for intermediate- and advanced-level services:</p> <ul style="list-style-type: none"> wheel or frame adjustments using tools to change seat angle; minimum adjustment range 10–15 °; if seat angle is independently adjustable, seat-to-backrest angle must also be adjustable. backrest to seat angle (recline) adjustments with or without the use of tools; minimum adjustment range 10–15 ° Backrest or back posts with adjustable height or supplied with a range of back post with a fixed height. <p>Additional requirements on adjustability for postural support for intermediate and advanced-level services:</p> <ul style="list-style-type: none"> removable backrest upholstery with back-post capabilities to accept third-party backrests. armrests with adjustable height, and short and full-length armpads; design and function of armrests should not restrict fitting of third-party backrests. <p>Frame size range:</p> <ul style="list-style-type: none"> seat width appropriate for a profile of users; includes child, adult and bariatric sizes with 25–50 mm increments. seat depth adjustable or with an option for seat extension or supplied with a range of seat frame depth options.
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2.2 Active dual-terrain wheelchair

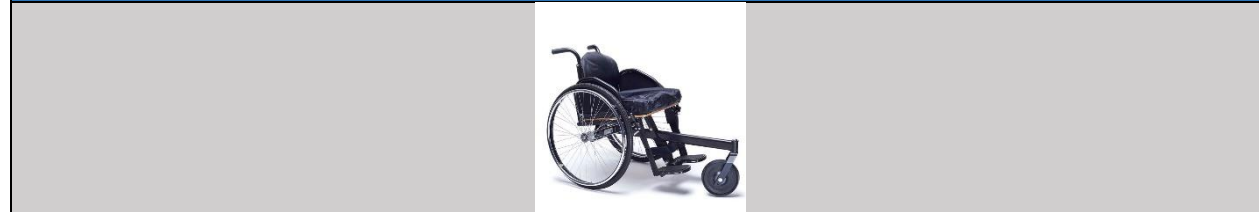


Typical user	Child or adult with basic, intermediate or advanced posture support needs
Specific characteristics	<p>Primarily for users who self-propel, but also for users who need assistance for use in indoor and outdoor uneven urban, peri-urban and rural environments Offers better outdoor mobility for users who do not have advanced wheelchair mobility skills</p> <p>Wheelchair with a folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests, and footrests</p>

	<p>Footrests positioned in line or behind front castors. Longer wheelbase and shorter or similar overall length than transport wheelchairs with large rear wheels Rear wheels and front castors appropriate for indoor and outdoor mixed terrain</p>
<p>Requirements for standard configuration</p>	<p>Frame:</p> <ul style="list-style-type: none"> • frame with mechanism(s) to fold or dismantle. • push handles can be integrated into the frame, supplied as an add-on component, or omitted if not required. • backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height. • backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back posts or with forward and backward and angle adjustment, including separate padded covers that can be mounted at different heights on back posts; quick-release mechanism to allow folding. • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchairs to accommodate people with shorter and longer legs. • two flip-up, swing-away, or removable footrests on folding frames • optional: armrests and clothing guards with minimal profile <p>Rear wheels:</p> <ul style="list-style-type: none"> • quick-release or removable without tools for rigid frames • quick-release or removable without tools for folding frames are optional. • camber ranges from 0 ° (rear wheel perpendicular to ground) to 1–3 ° (off from vertical) • diameter, appropriate for the size of the wheelchair, e.g., 508–660 mm • width e.g., 35–44 mm <p>Front castors:</p> <ul style="list-style-type: none"> • diameter and width variable: e.g., 203 x 50 mm, 102 x 76 mm <p>Range of size and width options available</p> <p>Puncture-proof or pneumatic rear tyres and front castors</p> <p>Frame and wheel adjustments:</p> <ul style="list-style-type: none"> • rear wheel or seat unit relative to wheelbase can be adjusted horizontally using tools. • front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through a range of different fixed-frame seat heights. <p>Optional for basic-level services but required for postural support for intermediate- and advanced-level services:</p>


	<ul style="list-style-type: none"> • wheel or frame adjustments using tools to change seat angle minimum adjustment range 10–15 °; if seat angle independently adjustable, seat-to-backrest angle must also be adjustable. • backrest to seat angle (recline) adjustments with or without tools minimum adjustment range 10–15 ° • mechanism or adjustment options available to maintain backward stability with maximum combined seat and backrest configuration adjustments. <p>Additional requirements on adjustability for postural support for intermediate and advanced-level services:</p> <ul style="list-style-type: none"> • removable backrest upholstery with back-post capabilities to accept third-party backrests. • armrests with adjustable height, and short and full-length armpads; design and function of armrests should not restrict fitting of third-party backrests. <p>Frame size range:</p> <ul style="list-style-type: none"> • seat width appropriate for a profile of users; includes child, adult and bariatric sizes with 25–50 mm increments. • seat depth adjustable or with an option for seat extension or supplied with a range of seat depth options.
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2.3 Active rough terrain wheelchair



Typical user	Child or adult with basic, intermediate, and advanced posture support needs to self-propel in rough outdoor terrain. Also, users who need assistance (excluding lever-propelled wheelchairs)
Specific characteristics	Wheelchair with folding or rigid frame; three, four or more wheels, with two larger drive wheels; seat and backrest; and footrests behind front castors Maybe lever-propelled. Similar or longer wheelbase than a dual-terrain wheelchair; larger overall length than transport wheelchair with large rear wheels Low centre of gravity to ensure stability. Rear wheels and castors appropriate for outdoor rough terrain
Requirements for standard configuration	Frame: <ul style="list-style-type: none"> • frame with mechanism(s) to fold or dismantle. • push handles can be integrated into the frame, supplied as an add-on component, or omitted. • integrated stability options for feet. • backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height. • backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back-posts or with

	<p>forward and backward and angle adjustment, including separate padded covers that can be mounted at different heights on back posts; quick-release mechanism to be removed to allow folding.</p> <ul style="list-style-type: none"> • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchairs to accommodate people with shorter and longer legs. • two flip-up, swing-away, or removable footrests on folding frames • optional: armrests and clothing guards with minimal profile <p>Rear wheels (manual propelling):</p> <ul style="list-style-type: none"> • with push-rims or lever-propelled • quick-release or removable without tools for rigid frames for transport; optional for wheelchairs with folding frame • camber minimum 3 ° (off from vertical) for stability • diameter, appropriate for the size and design of the wheelchair, e.g., 610–711 mm • width e.g., 35–44 mm • wider or larger-tread tyres <p>Front castors (manual propelling):</p> <ul style="list-style-type: none"> • diameter e.g., over 203 mm • width e.g., over 50 mm <p>Range of size and width options available</p> <p>Puncture-proof or pneumatic rear tyres and front castors</p> <p>Rear and front wheels (lever propelling):</p> <ul style="list-style-type: none"> • size and width of the front and rear wheels appropriate for rough terrain and wheelchair design, three or multiple wheels puncture-proof or pneumatic wheels <p>Frame and wheel adjustments:</p> <ul style="list-style-type: none"> • rear wheel axle or seat unit relative to wheelbase can be horizontally adjusted using tools. • front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through a range of different fixed-frame seat heights. <p>Optional for basic-level services but required for postural support for intermediate- and advanced-level services:</p> <ul style="list-style-type: none"> • wheel or frame adjustments using tools to change seat angle minimum adjustment range 10–15 °; if seat angle independently adjustable, seat-to-backrest angle must also be adjustable. • backrest to seat angle (recline) adjustments with or without the use of tools minimum adjustment range 10–15 ° • mechanism or adjustment options available to maintain backward stability with maximum combined seat and backrest configuration adjustments.
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	<p>Additional features and adjustability required for postural support for intermediate- and advanced-level services (optional for basic-level services):</p> <ul style="list-style-type: none"> removable backrest upholstery with back-post capabilities to accept third-party backrests. armrests with adjustable height, and short and full-length armpads; design and function of optional armrests should not restrict fitting of third-party backrests. <p>Frame size range:</p> <ul style="list-style-type: none"> seat width appropriate for a profile of users; includes child, adult, and bariatric sizes with 25–50 mm increments. seat depth adjustable or with an option for seat extension or supplied with a range of frame seat depth options.
<p>3. Wheelchairs, manual with postural support</p>	
<p>3.1 Wheelchair, manual with postural support (variable-position wheelchair)</p>	
	
<p>Typical user</p>	<p>Child or adult with intermediate or advanced posture support needs who requires variable tilt or recline, or a larger range of static tilt or recline than available on manual wheelchairs.</p> <p>For users who self-propel or need to be assisted</p> <p>For use in both indoor and uneven urban, peri-urban, and rural outdoor environments</p>
<p>Specific characteristics</p>	<p>Wheelchair with folding or rigid frame, three or four wheels, push-handles, rigid seat and backrest, armrests or tray table, and footrests</p> <p>Range of integrated or included PSDs and posture support cushion.</p> <p>Large-range adjustable recline and large-range adjustable and variable (dynamic) tilt.</p> <p>Rear wheels and front castors appropriate for indoor and outdoor mixed terrain</p>
<p>Requirements for standard configuration</p>	<p>Frame:</p> <ul style="list-style-type: none"> frame with mechanism(s) to fold or dismantle. rigid backrest and seat; removable without tools on folding frame adjustable tilt with minimum 20 ° without tools adjustable recline with minimum 20 ° with tools; optional variable (adjustable without tools) recline minimum 20 ° integrated mechanism or adjustment options to prevent tip-over when the chair is used with tilt or recline. footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchairs to accommodate people with shorter and longer legs; two flip-up, swing-away, or removable footrests for wheelchairs with folding frames.

- mechanism or adjustment options available to maintain backward stability with maximum combined seat and backrest configuration adjustments.
- for self-propelled wheelchairs: adjustment options to improve reach to rear.

Rear wheels:

- diameter, appropriate for the size of wheelchair, e.g., 559–660 mm for self-propelled wheelchairs or from 305 mm for assistant-propelled wheelchairs
- quick-release or removable without tools on rigid frames for self-propelled wheelchairs

Castors:

- diameter e.g., 76–203 mm
- width e.g., 13–50 mm
- may be larger and wider if only one castor (depending on terrain)


Range of size and width options available

Puncture-proof or pneumatic rear tyres and front castors

Integrated PSDs:

rigid backrest:

- separate padded cover designed to allow for modifications to optimize pelvis and trunk support.
- rigid pelvis and trunk side (lateral) supports are width (horizontal) and height (vertical) adjustable
- height adjustable or available in different lengths to optimize trunk support (at least at shoulder height or higher)
- not integrated into back-posts; separate component removable from back-posts if required, or part of integrated, removable seat–backrest unit.
- optional: rigid backrest independently adjustable from back-posts, with forward and backward and angle adjustments (see illustration in 2.1); can be mounted at different heights on back posts.
- headrest attached to the back of the backrest and with adjustable forward and backward, sideways, height and angle; must be able to support head behind, in line or in front of back support as required.
- pelvis strap (positioning belt) with adjustable length
- adjustable and removable knee separator pad (medial knee support); may be integrated into cushion; standard on child size and optional on adult size.
- calf or foot straps with adjustable length
- tray table or flip-up or removable armrests with adjustable height posture support cushion:
 - removable
 - matches wheelchair seat size configurations.

	<ul style="list-style-type: none"> ○ removable cover ○ can be modified to optimize pelvis, hip, and thigh support. ○ can be separately replaced. <p>Optional PSDs: outside (lateral) thigh or knee pads (supports) for a seat, shoulder harness and chest strap</p> <p>Size range:</p> <ul style="list-style-type: none"> ● seat width appropriate for a profile of users; includes child, adult and bariatric. ● sizes with 25–50 mm increments ● seat depth adjustable or supplied with a range of seat depth options of minimum 102 mm
3.2 Wheelchair, manual base frame only to be fitted with PSDs (variable-position wheelchair, base frame only)	
	
Typical user	<p>Child or adult with intermediate or advanced posture support needs who requires variable tilt or recline, or a larger range of static tilt or recline than available on manual wheelchairs.</p> <p>For users who self-propel or need to be assisted</p> <p>For use in both indoor and uneven urban, peri-urban and rural outdoor environments</p>
Specific characteristics	<p>Wheelchair with folding or rigid frame, three or four wheels, push-handles, rigid seat, armrests or tray table, footrests, and seat and back posts that can fit a range of PSDs.</p> <p>Large-range adjustable recline and large-range adjustable and variable (dynamic) tilt.</p> <p>Rear wheels and front castors appropriate for indoor and outdoor mixed terrain</p>
Requirements for standard configuration	<p>For intermediate and advanced service levels only:</p> <ul style="list-style-type: none"> ● frame with mechanism(s) to fold or dismantle. ● rigid seat; removable without tools on folding frame ● adjustable tilt with minimum 20 ° without tools (see illustrations in 3.1) ● adjustable recline with a minimum of 20 ° with tools (see illustrations in 3.1); optional variable (adjustable without tools) recline (seat-to-backrest angle adjustment) minimum 20 ° ● integrated mechanism or adjustment options to prevent tip-over when the chair is used with tilt or recline. ● back-posts with adjustable height or supplied with range of fixed-height options where back support is at least at shoulder height or higher; accepts range of third-party backrests. ● headrest to attach to third-party backrest; must be ordered separately with backrest.

	<ul style="list-style-type: none"> • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchairs to accommodate people with shorter and longer legs; two flip-up, swing-away, or removable footrests for wheelchairs with folding frames. • mechanism or adjustment options to maintain backward stability with maximum combined seat and backrest (back support) configuration adjustments. • for self-propelled wheelchairs: adjustment options to improve reach to rear wheels. <p>Rear wheels and castors:</p> <ul style="list-style-type: none"> • self-propelled rear wheels can be quick-release or removable without tools on rigid frames; optional for folding frames. • diameter appropriate for the size of wheelchair, e.g., 559–711 mm for self-propelled wheelchairs; from 203 mm for assistant-propelled wheelchairs <p>Front castors:</p> <ul style="list-style-type: none"> • diameter e.g., 76–203 mm • width e.g., 13–50 mm • may be larger and wider if only one castor (depending on the terrain) <p>Range of size and width options available</p> <p>Puncture-proof or pneumatic rear tyres and front castors</p> <p>Integrated PSDs:</p> <ul style="list-style-type: none"> • pelvis strap (positioning belt) with adjustable length • calf or foot straps with adjustable length • tray table or flip-up or removable armrests with adjustable height; design should not restrict fitting of third-party backrests. <p>Optional PSDs:</p> <ul style="list-style-type: none"> • outside (lateral) thigh or knee pads (supports) for the seat, shoulder harness and chest strap. • knee separator pad (medial knee support), adjustable and removable <p>Size range:</p> <ul style="list-style-type: none"> • seat width appropriate for a profile of users; includes child, adult, and bariatric sizes with 25–50 mm increments. • seat depth adjustable or supplied with a range of seat depth options of a minimum 102 mm
<p>General design requirements</p> <p>The wheelchair must meet the user’s needs (enable effective mobility, transfers, transport) environmental conditions (indoor and outdoor mobility over local terrain), provide postural support (appropriate size, adjustments, and posture-support options), and be safe and durable.</p>	
<p>Standards</p>	

EN 12183:2014 Manual Wheelchairs – Requirements and Test Methods (or a more recent version or equivalent)

ISO 7176–1 Wheelchairs – Part 1: Determination of Static Stability

ISO 7176–3 Wheelchairs – Part 3: Determination of Effectiveness of Brakes

ISO 7176–5 Wheelchairs – Part 5: Determination of Dimensions, Mass and Manoeuvring Space

ISO 7176–7 Wheelchairs – Measurement of Seating and Wheel Dimensions

ISO 7176–8 Wheelchairs – Part 8: Requirements and Test Methods for Static, Impact, and Fatigue Strengths

ISO 7176–15 Wheelchairs – Requirements for Information Disclosure, Documentation, and Labelling

ISO 7176–16 Wheelchairs – Part 16: Resistance to Ignition of PSDs.

Specific product standards for manual wheelchairs to be used as seating in a motor vehicle:

ISO 7176–19:2008 Wheeled Mobility Devices for Use as Seats in Motor Vehicles or Equivalent (test should be executed with head support attached to a wheelchair)

Current product standards for posture-support devices:

ISO 16840–3 Wheelchair Seating: Part 3: Determination of Static, Impact and Repetitive Load Strengths for PSDs

Size and weight

Information about the overall width, height and length of a manual wheelchair, seat depth and width, and backrest (back support), armrest (arm support) and footrest (foot supports) height must be provided. If applicable, adjustment ranges and dimensions in operating and folded modes must be provided. Overall weight of the wheelchair and its configuration when weighed must be provided. Rear wheel and front castor diameter and width must be provided. The user's maximum weight capacity should be indicated for each type and size of the wheelchair.

Accessories and spare parts

The following optional wheelchair mobility accessories, add-ons and spare parts may be procured for active wheelchairs. To ensure mobility accessories are compatible with a particular wheelchair, they must be added to the "requirements for standard configuration" section for the relevant wheelchair:

- Removable large-diameter castor: for users of active manual four-wheel wheelchairs to improve outdoor access over long distances or uneven terrain. Raises front castors and turns wheelchair into three-wheel device. Swivel castor is detachable and has a large diameter; it can be quick-release or removable without tools. Castor attaches to footrests or frame. The storage bracket is attached to the frame. Additional adaptor bar to be included for the folding frame. Complete with all attachments for storage and use.
- One-arm drive unit: for users of manual wheelchairs who have limited or no arm and hand function on one side of their body. Designed to be self-propelled with one hand or arm only. The unit consists of two push-rims on one side. Each push-rim can be used independently to change direction or be used together to go in a straight line. To clamp onto the wheelchair frame: if it is a folding frame, the unit should fold with it when attached. Width is adjustable or supplied with a range of options.
- Clamp-on propelling lever: for users of wheelchairs who are travelling long distances over uneven terrain. Designed to require less force to move the wheelchair. Left and right levers are attached to rear wheels with a mechanism designed to allow wheel propulsion via levers.

replacing push rim propulsion. A gearing system can be used to allow easier propulsion up steep slopes or faster propulsion on flat ground. Left and right arm levers and attaching mechanisms allow forward movement of the manual wheelchair.


- Removable trike attachment: for users of active manual wheelchairs to improve efficiency over long distances. Designed to be self-propelled by users. The attachment is removable to allow wheelchair access to small spaces such as buildings and homes. The attachment/detachment mechanism should be quick-release or removable without tools. When connected, the trike attachment lifts the front castor wheels off the ground when locked in place. Hand-powered drive train to the front drive wheel.

Add-on PSDs include (but are not limited to):


- tension-adjustable backrests with range of back height options;
- rigid backrests with no or low-profile side (lateral) support with an option to fit with additional trunk side (lateral trunk) support, or both trunk and pelvis side (lateral) supports (range of back height options/adjustability);
- rigid backrests with medium (extending to mid-axilla line) or deep profile (extending to the front of the body) to provide an appropriate level of trunk or pelvis support (range of back height options/adjustability);
- headrests;
- tray tables;
- range of arm supports;
- range of thigh supports; range of footrests with seat-to-lower leg support angle and lower leg support-to-foot support angle options/adjustability;
- range of straps or harnesses for a trunk, pelvis, thighs, lower legs, and feet;
- outside (lateral) thigh or knee pads (supports) for the seat;
- adjustable and removable knee separator pad (medial knee support).

Each item should have an appropriate range of adult and child sizes and match the wheelchair configuration. Mounting systems should be included where appropriate.

Prosthesis	
Name of product	Prosthesis
Description and intended use.	To replace a or both missing limbs and another body part.
General Features	Transtibial, Transfemoral, Transradial, Joint disarticulation Prosthesis. Adjustable Joint, (SACH) foot, soft ankle cushion heel, Shank, Adapters, Knee and Elbow component, Sucks, Silicon Liner, Belt.
Keywords	Transtibial, Transfemoral, Transradial, Joint disarticulation Prosthesis
Functional requirements	

Prosthesis	
	
Typical user	Child or adult have missing extremities that are unable to walk from one place to another. Help with performance for children or adult with missing upper or lower limbs and enhance minimal or no support.
General design requirements Must be lightweight and easy to fit and take off. Enhance easy movements at the joint. Facilitates engagement in functional and recreational activities	
Size and Weight Lightweight for mobility.	
Technical Information (for service providers) Manual guidance in form of pictures and scripts should be provided for service providers.	
Instructions for Users (users and caregivers) Technical supervision is required before delivery and review after two months. A referral point must be identified before delivery especially when a patient lives in another community from the center of fitting.	
Environment for Use Must withstand weight, terrain, and weather.	
Warranty One to two years	
Lifespan Variable	
Packaging, Labelling and State of Assembling Manual guide to be provided to help fit the device. A guide must be clearly written or in picture format.	
Accessories and Spare Parts Cosmetic socks, screws, and bolts. Tools to fit knots, velcros etc.	

Standing Frames	
Name of product	Standing Frames
ISO 9999 code	44808
Description and intended use. Can be wooden or metal that aids people in standing upright. Made up of upper body support, pelvic and lower limb support. Has a flat board or metal at the base that helps with the positioning of feet. Has a table positioned in front to help with upper body and limb activities. May be fitted with straps for stability.	
General Features Upper body, trunk, pelvic and lower body support.	

<p>All the various support parts must be adjustable. The base must be flat for proper footrest and contact. Must be firm and stable to accept weight.</p>	
<p>Inclusion Wooden or metal forms</p>	
<p>Exclusion Zimmer frames.</p>	
<p>Keywords Flat base, front plate/table, side support.</p>	
<p>Functional requirements</p>	
<p>Standing Frames</p>	
	
<p>Typical user</p>	<p>For short- and long-term use for children and adults with balance and standing impairments To create more power for those with lower limb weakness to maximize functional use of upper limbs, and to provide stability.</p>
<p>General design requirements Strong and durable, sufficiently stable Easy to move around (some have wheels) Straps can be easily replaced or repaired and are easily available in the local market.</p>	
<p>Standards Labelling and instruction for assembly and use</p>	
<p>Certificate of Conformity Must be provided by the service provider.</p>	
<p>Size and Weight Must be light in weight but firm.</p>	
<p>Technical Information (for service providers) Manuel guide/pictures/scripts.</p>	
<p>Instructions for Users (users and caregivers) From the manual</p>	
<p>Environment for Use Safe terrain, flat surface, can stand harsh weather.</p>	
<p>Warranty Wood- One year Metal- two years</p>	
<p>Lifespan Depends on the use of the user and the environment</p>	
<p>Packaging, Labelling and State of Assembling Must be assembled using instructions from the manual before use.</p>	
<p>Accessories and Spare Parts Bolts and knots Screws and straps with screwdrivers, staple gums and pins, and tables.</p>	

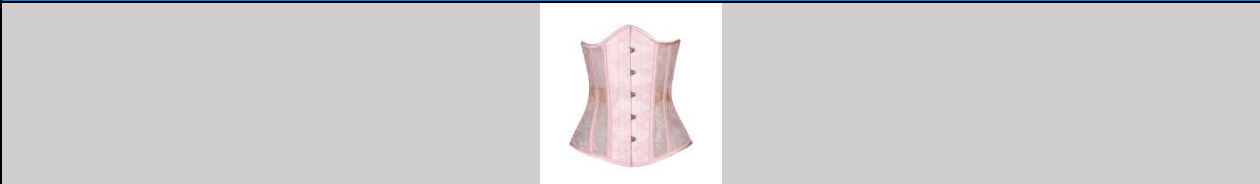
Velcros and cushions for comfort.

Corset

Name of Product Corset
Description and intended use. They are corrective devices used on the spinal column. They are used for children and adults.
General Features Some are made up of plastic and fabrics.
Inclusion CTLSO, TLSO, TLSO body jacket, Lumbo sacral Corset belt
Exclusion Poor materials which are non-elastic.
Keywords Corset, TLSO body jacket, Lumbo sacral.

Functional requirements

Corset



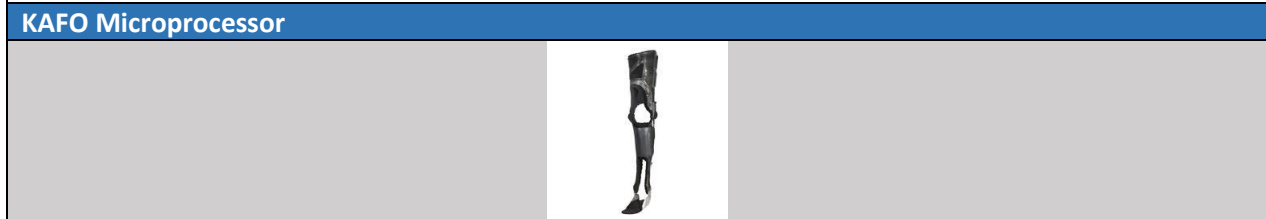
Typical user	Children and adults with typical spine injuries and spinal deformities Specific character: Support and immobilize the affected areas along the spine.
General design requirements	It should be easy to carry, flexible, comfortable and to carry out its intended purpose.
Certificate of Conformity	Should come from the manufacturer
Size and Weight	Depends on the individual's weight and size.
Technical Information (for service providers)	From the Manual
Instructions for Users (users and caregivers)	Technicians should train the users/caregivers
Environment for Use	In a conducive area
Warranty	Six Months
Lifespan	One year
Packaging, Labelling, and State of Assembling	Must be delivered assembled.

Accessories and Spare Parts
Reverts and caps, Velcro, buckles, fabrics etc.
Other Products Requirements
Soft Cushion.

KAFO Microprocessor


Name of product	KAFO Microprocessor
Description and intended use.	It is used for children and adults with neuro muscular malfunctions.
General Features	It provides support and correction to the knee ankle and foot.
Inclusion	Electronic KAFO-Quality bars and plastic leathers, Plastic, metal, Velcro buckles, Velcro caps, glue. Polypropylene and affordable.
Exclusion	Poor materials.
Keywords	Reverts and cap, glue,

Functional requirements




Typical user	Mobility, support, accommodate stabilization, correction and maintenance.
General design requirements	Specification by referral person or prescription. It may need a knee joint or no joint.
Certificate of Conformity	Producer or manufacturer
Size and Weight	Light and rigid
Technical Information (for service providers)	Technicians advise and train users.
Instructions for Users (users and caregivers)	Technicians should provide the information
Environment for Use	Accessible environment
Warranty	One year
Lifespan	Five years


Packaging, Labelling and State of Assembling Delivered on the spot
Accessories and Spare Parts Velcro, kneebar, leather, buckle, knee joints, polypropylene, metal sheet, aluminium plates, and plastic.

AFO	
Name of product AFO	
Description and intended use. Ankle foot orthosis is an external mechanical device utilized on the lower limb to stabilize the ankle joint, and improve the joint and physical function of the foot. It is used to improve walking patterns by reducing, preventing, or limiting movement of the lower leg and supporting weak muscles.	
General Features It is of plastic made with straps and buckles, velcros.	
Inclusion Quality plastic, leather, polypopline and affordable	
Exclusion Poor materials.	
Keywords Polypropylene, metal, Velcro buckles, reverts, caps, glue, thinner.	
Functional requirements	
AFO	
	
Typical user	Mobility support, accommodation, stabilization, correction and maintenance.
Certificate of Conformity Producer or manufacturer	
Size and Weight Light and rigid	
Technical Information (for service providers) Technicians advise and train users	
Instructions for Users (users and caregivers) Technicians should provide the information	
Environment for Use Accessible environment	
Warranty One year	


Lifespan Five years
Packaging, Labelling and State of Assembling Delivered on the spot
Accessories and Spare Parts Velcro, kneebar, leather, buckle, knee joints, polypropylene, metal sheet, aluminium plates, and plastic.

PET	
Name of product PET	
	
Description and intended use. It is a mobility device that is used by people with physical mobility impairment.	
General Features It is made up of wood, metal frames, axle, tyres, rachets, crang handles, chains, fabrics, paint, bolt and nuts, screws, etc.	
Inclusion Mobility Cart, motorized engine	
Exclusion Manuel energy.	


CTLSO	
Name of product CTLSO	
ISO 9999 code ISO 8549	
Description and intended use. CTLSO orthosis not only allows compression, expansion, and adjustability but secures the patient from the neck, down to the spine.	
General Features It is made up of leather, fabrics or plastics	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	
Functional requirements	

CTLSO	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	


TLSO Boston	
Name of product TLSO Boston	
ISO 9999 code ISO 9001	
Description and intended use. It can either be used for support, correction and immobilisation. It can also be used for cosmetics.	
General Features It is made up of leather, fabrics or plastics	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	

Functional requirements	
TLSO Boston	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	


TLSO body jacket	
Name of product TLSO body jacket	
Description and intended use. It can either be used for support, correction and immobilisation. It can also be used for cosmetics.	
General Features It is made up of leather, fabrics or plastics	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	

Functional requirements	
TLSO body jacket	
	
Typical user	Polio victims, Cerebral Palsy Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, lightweight metal bars, aluminium bars	


Lumbo sacral corset belt	
Name of product Lumbo sacral corset belt	
Description and intended use. It can either be used for support, correction and immobilisation. It can also be used for cosmetic	
General Features It is made up of leather, fabrics and, plastics,	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	
Functional requirements	

Lumbo sacral corset belt	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	


Elbow orthosis static	
Name of product Elbow orthosis static	
ISO 9999 code ISO 8549	
Description and intended use. It can either be used for support, correction and immobilisation. It can also be used for cosmetics.	
General Features It is made up of leather, fabrics and, plastics,	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	

Functional requirements	
Elbow orthosis static	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	


LSO - rigid brace	
Name of product LSO - rigid brace	
ISO 9999 code ISO 13485	
Description and intended use. It can either be used for support, correction and immobilisation. It can also be used for cosmetics.	
General Features It is made up of leather, fabrics and, plastics,	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	

Keywords	
Nylon, syntenic leather, stick, or wood	
Functional requirements	
LSO - rigid brace	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements	
It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity	
Producer	
Size and Weight	
Light and easy to carry.	
Technical Information (for service providers)	
Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers)	
Technicians to advise and train users or caregivers	
Environment for Use	
Accessible	
Warranty	
One Year	
Lifespan	
One Year	
Packaging, Labelling and State of Assembling	
Delivered on the spot	
Accessories and Spare Parts	
screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	


Ash brace	
Name of product	
Ash brace	
ISO 9999 code	
ISO 18122	
Description and intended use.	
It provides stabilization of the spine and encourages cervical and lumbar lordosis thus relieving pressure on the anterior parts of the vertebral bodies.	
General Features	


It is made up of leather, fabrics and, plastics,	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	
Functional requirements	
Ash brace	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	

Taylor's brace	
Name of product Taylor's brace	
Description and intended use.	


A Taylor's Brace maintains the spine in neutral position when sitting, standing or walking and hence helps in posture correction.	
General Features It is made up of leather, fabrics and, plastics,	
Inclusion Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion Nylon, syntenic leather, stick, or wood	
Keywords Nylon, syntenic leather, stick, or wood	
Functional requirements	
Taylor's brace	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements A Taylor's Brace maintains the spine in neutral position when sitting, standing or walking and hence helps in posture correction.	
Certificate of Conformity Producer	
Size and Weight Light and easy to carry.	
Technical Information (for service providers) Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers) Technicians to advise and train users or caregivers	
Environment for Use Accessible	
Warranty One Year	
Lifespan One Year	
Packaging, Labelling and State of Assembling Delivered on the spot	
Accessories and Spare Parts screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	

Williams brace

Name of product	
Williams brace	
ISO 9999 code	
ISO 13485	
A Brace maintains the spine in neutral position when sitting, standing or walking and hence helps in posture correction. It can also be used after surgery.	
General Features	
It is made up of leather, fabrics and, plastics,	
Inclusion	
Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion	
Nylon, syntenic leather, stick, or wood	
Keywords	
Nylon, syntenic leather, stick, or wood	
Functional requirements	
Williams brace	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements	
It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity	
Producer	
Size and Weight	
Light and easy to carry.	
Technical Information (for service providers)	
Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers)	
Technicians to advise and train users or caregivers	
Environment for Use	
Accessible	
Warranty	
One Year	
Lifespan	
One Year	
Packaging, Labelling and State of Assembling	
Delivered on the spot	
Accessories and Spare Parts	
screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	

Ischial weight bearing/ relieving KAFO	
Name of product	
Ischial weight bearing/ relieving KAFO	
ISO 9999 code	
ISO 9241	
It can either be used for support, correction and immobilisation.	
General Features	
It is made up of leather, fabrics or plastics	
Inclusion	
Fabrics, leather, plastics, sidebars, Velcro, buckle	
Exclusion	
Nylon, syntenic leather, stick, or wood	
Keywords	
Nylon, syntenic leather, stick, or wood	
Functional requirements	
Ischial weight bearing/ relieving KAFO	
	
Typical user	Polio victims, Cerebral Pluses Cases, stroke cases, trauma cases, congenital cases. Specific character: Support and correct the affected legs or lower extremities (Legs and foot).
General design requirements	
It can be used with aluminium bands, polypropylene, animal leather, metal bars.	
Certificate of Conformity	
Producer	
Size and Weight	
Light and easy to carry.	
Technical Information (for service providers)	
Technicians to advise and train users or caregivers.	
Instructions for Users (users and caregivers)	
Technicians to advise and train users or caregivers	
Environment for Use	
Accessible	
Warranty	
One Year	
Lifespan	
One Year	
Packaging, Labelling and State of Assembling	
Delivered on the spot	
Accessories and Spare Parts	
screws, bolts, buckles, reverts, appropriate leather, light weight metal bars, aluminium bars	

3.2 Vision

Ready-to-wear spectacles for near vision (reading glasses)	
Name of product Spectacles; low vision, short distance, long distance, filters, and protection	
ISO 9999 code 22 03 06 Spectacles and contact lenses	
Description and intended use. Ready-to-wear spectacles for near vision are plus-powered lenses mounted into a spectacle frame. They are commonly known as reading glasses. They are intended for use by adults with presbyopia, helping them to visually focus on near tasks such as reading, writing, sewing or cooking.	
General Features Reading glasses comprise lenses with power in the range of +0.75D to +4.00D. Left and right lenses have the same plus power and are single-vision lenses (distribute focus evenly across the lens surface). Reading glasses are available in different frame sizes and styles, with no adjustability or customizing	
Inclusion Near-vision ready-to-wear spectacles (reading glasses)	
Exclusion All other types of spectacles, including spectacles for people with myopia, hyperopia, astigmatism and low vision	
Keywords Visual impairment, presbyopia, near tasks	
Functional requirements	
1. Near vision ready-to-wear spectacles	
	
Typical user	Adults with presbyopia needing plus-powered lenses for near-vision tasks such as reading, writing, sewing or cooking
Specific characteristics	Full-field and half-eye frames
Requirements for standard configuration	Lens power range +0.75D to +4D with 0.25D interval Lens material: plastic or glass Solar UV transmittance: UV absorption should be 95% and above close to 400 nm
General design requirements The frame of the reading glasses should be durable and lightweight. The lens should be impact- and scratch resistant. The lens diameter should depend on the lens design and frame size.	
Standards ISO 16034:2002 Ophthalmic Optics – Specifications for Single Vision Ready-to-wear Near-vision Spectacles EN 14139:2002 Ophthalmic Optics – Specifications for Single Vision Ready-to-wear Near-vision	

Spectacles US ANSI standard: Z80.31–2017 Specifications for Ready-to-wear Near-vision Spectacles
Size and weight The supplier should provide the following information: <ul style="list-style-type: none"> • frame dimensions, including eye size (lens width), bridge width, temple (arm) length and lens height • optical centration distance • overall weight
Accessories and spare parts The following accessories should be supplied as standards: <ul style="list-style-type: none"> • individual box, case or pouch for each pair of reading glasses; • cleaning cloth for each pair of reading glasses.
Other product requirements The lens power should be labelled on each pair of glasses The following additional information should also be provided by the supplier: <ul style="list-style-type: none"> • Lens type and material • Lens coating • Frame material and colour • Frame colour

Manual Braille writing equipment
Name of product Braille writing equipment/Brailler
ISO 9999 code 22 12 12 Manual Braille writing equipment
Description and intended use. Braille writing equipment is used to produce embossed Braille characters on paper. They are intended for use by children and adults with blindness or low vision.
General Features The equipment consists of a manually operated slate or frame with Braille cells and a special-tipped object called a stylus. The slate or frame is usually metal or plastic, with two plates hinged together on the top or side to hold papers for writing Braille. A stylus consists of a short rod with a blunted point to emboss Braille dots. It is typically about 5 cm long with a metal tip and a small handle gripped by the index finger and thumb for embossing the Braille dot into the page.
Inclusion Braille slates/frames Interline Braille writing slates/frames Interpoint Braille writing slates/frames small pocket frames Stylus of different types
Exclusion Electric/electronic/digital Braille writing devices Boards
Keywords Braille writing, interline, interpoint, slate/frame, stylus
Functional requirements
1. Braille slate/frame with a board and marker



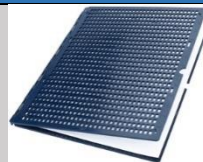
Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	Board/frame of A4 size with 30 cells x 27 lines Marker after every 5 cells Metal guide and board with up to 9 holes for fitting guide Plastic Frame.

2. Interline Braille slate/frame



Typical user	Child or adult with blindness or low vision
Specific characteristics	Capacity to emboss Braille on both sides of paper, where alternate lines are embossed front and back
Requirements for standard configuration	30 cells x 27 lines Marker after every 5 cells


3. Interpoint Braille slate/frame




Typical user	Child or adult with blindness or low vision
Specific characteristics	Capacity to emboss Braille on both sides of paper, where space between dots on front side is used when embossed on the back
Requirements for standard configuration	Up to 30 cells x 27 lines Marker after every 5 cells

4. Small pocket frame



Typical user	Child or adult with blindness or low vision
Specific characteristics	Much smaller and extremely portable
Requirements for standard configuration	Up to 8 or 10 lines with a maximum of 20 cells per line
5. Stylus of knob, flat or saddle type	
	
Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	Plastic head with a metal pin at bottom 5.72 cm long with 27.94–40.64 cm metal tip
<p>General design requirements</p> <p>The dots of each cell must be easily discernible by touch. The height of the dots must be sufficient to be easily distinguished from the background. The board or frame should be lightweight, easy to open and close to hold the paper in place, and self-locking to hold the paper. The stylus should be lightweight and able to be firmly and comfortably gripped by the index finger and thumb for embossing.</p>	
<p>Standards</p> <p>None</p>	
<p>Size and weight</p> <p>Weight, length and width of the frame, slate or board should be provided</p>	
<p>Warranty</p> <p>One Year</p>	
<p>Lifespan</p> <p>One year</p>	
<p>Accessories and spare parts</p> <p>The following accessories should be required:</p> <ul style="list-style-type: none"> • case for stylus. 	

Mechanical Braille typewriters	
Name of product	Braille writing equipment/Braillers
ISO 9999 code	22 12 15 Typewriters
Description and intended use.	Braille typewriters (Braillers) are mechanical (hand-operated) devices used for writing Braille by pressing related keys onto paper. Braillers are intended to support communication for children and adults with blindness or low vision and for Braille transcribers to write in Braille.

General Features	
A Braille has a hard casing and a keypad. Braille letters are indented into Braille paper by pressing one of the six Braille keys.	
Inclusion	
Mechanical Perkin Braille	
Exclusion	
Euro type Braille, Tatrapoint Braille, Electric/electronic Braille, Unimanual Braille, Large cell Braille, Smart Braille, and Extension keys are excluded	
Keywords	
Braille, Braille reading, Braille writing	
1. Standard Perkins Braille	
	
Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	<p>Closed body architecture (to prevent dust accumulation)</p> <p>Braille dots to be even 42 cells per line with up to 30 lines per page</p> <p>Braille functions:</p> <ul style="list-style-type: none"> • keypad – six Braille keys, one space key, one backspace key and one line changing key • margins – full right and left margin adjustment to accommodate given paper size and line centring • bell – audible bell sounds, 7 spaces before the end of the line • carriage – carriage release, full horizontal movement between margin stops <p>Dot specification:</p> <ul style="list-style-type: none"> • dot height 0.048 cm • dot diameter 0.144 cm • dot spacing 0.228 cm • character spacing 0.609 cm • line spacing 1.016 cm
General design requirements	
The Braille must be durable, easy to operate and be upward writing (dots on the same side of the paper). The Braille should have an ergonomically designed keypad and be much less fatigue-inducing (compared with slate and stylus). Parts of the Braille should be easy to replace when required. The Braille is compatible with standard Braille paper.	

Standards	None
Lifespan	The product should have a lifespan of at least 10 years
Accessories and spare parts	The following accessories should be procured: <ul style="list-style-type: none"> • dust covers.



Optical magnifiers



Name of product	Magnifiers, optical
ISO 9999 code	ISO 22 03 09 Magnifier glasses, lenses, and lens systems for magnification
Description and intended use.	Optical magnifiers can produce magnified (enlarged) images of close objects and print. They are intended for use by children and adults with low vision that cannot be fully corrected with spectacles or other treatments such as surgery.
General Features	An optical magnifier uses a positive power lens to produce a magnifying effect. It comprises a single lens or more than one lens (lens system). Most lenses or lens systems are mounted into a frame, with the exception of a dome magnifier. Different frame types suit different tasks. The range of magnifying power (magnification) is measured in dioptres (D). Magnifiers most commonly have a lens power range from +4D to +76D. Some magnifiers include a built-in light source and are described as illuminated magnifiers.
Inclusion	Handheld, stand magnifiers, pocket, dome, sheet, spectacle and other portable magnifiers. Magnifiers with or without illumination
Inclusion	Handheld, stand magnifiers, pocket, dome, sheet, spectacle and other portable magnifiers Magnifiers with or without illumination Telescopes
Keywords	Low vision, visual impairment, sight enhancement

Functional requirements

1. Non-illuminated stand magnifier

	
Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Supports around lens mount should be small or transparent to avoid blocking light from the area being viewed Smaller supporting stands can expose more area for better spot-writing function

	Some stand magnifiers have an adjustable lens to compensate for user's uncorrected refractive error
Requirements for standard configuration	<p>Lens power range +6D to +76D</p> <p>Lens diameter: 11 minimum lens diameter is described below, as greater than or equal to (\geq):</p> <ul style="list-style-type: none"> $\leq +8D$: ≥ 90 mm $> +8D$ to $+12D$: ≥ 80 mm $> +12D$ to $+16D$: ≥ 60 mm $> +16D$ to $+20D$: ≥ 45 mm $> +20D$ to $+26D$: ≥ 35 mm $> +26D$ to $+40D$: ≥ 30 mm $\geq +40D$: ≥ 26 mm <p>Lens: plastic</p> <p>Frame (mount): high-grade plastic</p>
2. Illuminated stand magnifier	
	
Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Same as non-illuminated stand magnifier with in-built illumination distributed evenly across the area being viewed
Requirements for standard configuration	<p>Lens power range +6D to +76D</p> <p>Minimum lens diameter is described below, as greater than or equal to (\geq):</p> <ul style="list-style-type: none"> $\leq +8D$: ≥ 90 mm $> +8D$ to $+12D$: ≥ 80 mm $> +12D$ to $+16D$: ≥ 60 mm $> +16D$ to $+20D$: ≥ 45 mm $> +20D$ to $+26D$: ≥ 35 mm $> +26D$ to $+40D$: ≥ 30 mm $\geq 40D$: ≥ 26 mm <p>Lens: plastic</p> <p>Frame (mount): high-grade plastic</p> <p>Illumination options for illuminated magnifiers: light-emitting diode (LED), surface-mounted diode (SMD) LED or incandescent bulbs</p>
3. Non-illuminated handheld magnifier	
	
Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific	Magnification can be adjusted by changing the distance between the magnifier

characteristics	<p>and the object being viewed; this can also help to compensate for uncorrected refractive error</p> <p>Available as a lens held in a round frame with a handle, pocket magnifiers, chest support magnifiers and pendant magnifiers</p>
Requirements for standard configuration	<p>Lens power range: +4D to +56D</p> <p>Minimum lens diameter is described below, as greater than or equal to (\geq):</p> <ul style="list-style-type: none"> $\leq +8D$: ≥ 90 mm $> +8D$ to $+12D$: ≥ 80 mm $> +12D$ to $+16D$: ≥ 60 mm $> +16D$ to $+20D$: ≥ 45 mm $> +20D$ to $+26D$: ≥ 35 mm $> +26D$ to $+40D$: ≥ 30 mm $\geq +40D$: ≥ 26 mm <p>Lens: plastic</p> <p>Frame (mount) and handle: high-grade plastic</p>
4. Illuminated handheld magnifier	
	
Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Same as a non-illuminated handheld magnifier with in-built illumination distributed evenly across the area being viewed
Requirements for standard configuration	<p>Lens power range: +4D to +56D</p> <p>Minimum lens diameter is described below, as greater than or equal to (\geq):</p> <ul style="list-style-type: none"> $\leq +8D$: ≥ 90 mm $> +8D$ to $+12D$: ≥ 80 mm $> +12D$ to $+16D$: ≥ 60 mm $> +16D$ to $+20D$: ≥ 45 mm $> +20D$ to $+26D$: ≥ 35 mm $> +26D$ to $+40D$: ≥ 30 mm $\geq 40D$: ≥ 26 mm <p>Lens: plastic</p> <p>Frame (mount) and handle: high-grade plastic</p> <p>Illumination options for illuminated magnifiers: LED, SMD LED or incandescent bulbs</p>
5. Spectacle magnifier	
	
Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error

Specific characteristics	Lens or lens system mounted into spectacle frames Enables binocularity when base-in prisms are incorporated, to offer better field of view
Requirements for standard configuration	Lens power: <ul style="list-style-type: none"> • single-vision lens power range +4D to +24D • single-vision lens with prismatic power for binocular viewing range +4D to +10D Frame: high-grade plastic Solar UV transmittance: UV absorption should be 95% and above close to 400 nm
General design requirements	
The magnifier lenses should be lightweight, have a protective coating against scratches, and be impact resistant. Lenses are preferably aspheric for better image quality without spherical aberrations. The lens mount and body of the magnifier should be made of high-quality, durable material. Built-in illumination could be an option to provide adequate light to suit the task. The battery compartment of the illuminated magnifiers should allow easy battery changes. Regular and rechargeable battery options should be available (e.g. high-capacity nickel metal hydride batteries). LED or SMD LED bulbs are preferred over incandescent bulbs as they provide a brighter, longer-lasting light. The bulb should be shock-resistant and non-heat-generating. The magnifier should be ergonomic for use or wear, and the overall design should be user-friendly	
Standards	
ISO 11.040.70 Ophthalmic Equipment Including Ophthalmic Implants, Glasses, Contact Lenses and Other Cleaning Products ISO 15253: 2000 Ophthalmic Optics and Instruments – Optical Devices for Enhancing Low Vision	
Environment of use	
The product should withstand room temperature.	
Lifespan	
The product should have a lifespan of at least three years	
Accessories and spare parts	
The following accessories are required: <ul style="list-style-type: none"> • pouches for magnifiers 	

White canes	
Name of product	White canes
ISO 9999 code	12 39 03 Tactile sticks or white canes
Description and intended use.	White canes are long rod-like devices intended for use by children and adults with blindness or low vision. They give the user information about the environment they are moving through, such as obstacles in their path, stairs they are coming to, curb edges they are approaching, and many other aspects of their environment that must be dealt with.
General Features	

A white cane has a handle on one end and a tip or roller on the other. The handle may have a wrist loop to hang the cane up when not in use. The body of the white cane is covered with reflective tape to make the user-visible.
 Some white canes have a section of red or yellow paint or reflective tape at the tip to indicate the user is blind. Some canes have alternating colours of white and red indicating both vision and hearing loss.

Inclusion
 Straight, angular or folding white canes

Exclusion
 White canes with electronic or ultrasonic features

Keywords
 White canes with electronic or ultrasonic features

Functional requirements

1. Straight white cane



Typical user | Child or adult with blindness or low vision who can walk independently with ease

Specific characteristics | Cane with straight tubing

Requirements for standard configuration | Aluminum, fibreglass, or carbon fibre straight tubing with an outer diameter 1.2 cm or smaller
 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick
 Length range:
 • tall adults: 145 cm ± 5 cm
 • adults: 120–140 cm ± 5 cm
 • children: 70 cm ± 5 cm
 Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and wrist loop


2. Angular white cane



Typical user | Child or adult with blindness or low vision who can walk independently with ease



Specific characteristics | Cane with straight tubing with bent handgrip


Requirements for standard configuration | Aluminum, fibreglass or carbon fibre straight tubing with an outer diameter 1.2 cm or smaller
 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick.
 Length range:
 • tall adults: 145 cm ± 5 cm
 • adults: 120–140 cm ± 5 cm
 • children: 70 cm ± 5 cm

	Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and bent at 150 ° from the main body of the cane, and wrist loop
3. Folding white cane	
	
Typical user	Adults with blindness or low vision who can walk independently with ease
Specific characteristics	Cane with foldable tubing
Requirements for standard configuration	Foldable aluminium, fibreglass or carbon fibre tubing with an outer diameter of 1.2 cm or smaller; with four or five folds; and with an elastic cord running through the middle of the tubing 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick Length of the cane after connecting joints should be 140 cm for adults Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and wrist loop
General design requirements	
The white cane should be strong, durable, and lightweight to withstand wear and tear during travel. Its parts should be replaceable. The elastic cord used in a folding cane should be durable. The tip should be made of durable material and be a good insulator of electricity.	
Size and weight	
Information about the length of the white cane should be required; if applicable, include dimensions in operating and folded modes For straight canes, minimum and maximum lengths with types of handles should be provided. For folding canes, the minimum and maximum number of folds and lengths should be provided	
Environment of use	
White canes should withstand various terrain.	
Accessories and spare parts	
The following spare parts should be required: <ul style="list-style-type: none"> • white cane tips; • elastic cords (for foldable white canes only). 	

3.3 Hearing

Hearing loops	
Name of product	Hearing loops
ISO 9999 code	

22 18 24 Radio frequency transmission systems	
22 18 30 Induction loop devices	
Description and intended use. Personal remote microphone systems improve the signal-to-noise ratio (SNR) for children and adults with hearing difficulties to overcome the negative effects of talker distance, ambient noise and reverberation in an environment (e.g., in a school classroom).	
General Features The system comprises a wireless transmitting microphone worn by the speaker and personal receiver(s) worn by the listener. The system sends signals directly from the microphone and transmitter to the receiver. The system operates on frequency modulation (FM) or digital modulation (DM).	
Inclusion Radio transmitters with built-in or external microphone Receivers for compatible hearing aids and cochlear implant	
Exclusion Hardwired microphone/receiver systems AM, shortwave radio, and infrared-based systems	
Keywords Ambient noise, digital modulation (DM), direct audio input (DAI), frequency modulation (FM), induction loop, reverberation, signal-to-noise-ratio (SNR), talker distance, T-coil	
Functional requirements	
1. Transmitter with Microphone	
	
Typical user	Speaker who communicates with a child or adult with compatible hearing aids and cochlear implants in certain environments (e.g., classroom).
Specific characteristics	Worn by a speaker.
Requirements for standard configuration	An internal or external microphone that allows placement near the speaker's mouth or clipped at the chest and operated by a rechargeable or disposable battery.
2. Receiver with direct audio input (DAI)	
	
Typical user	Child or adult with a compatible hearing aid or cochlear implant
Specific characteristics	Plugged into a hearing aid or external part of a cochlear implant

Requirements for standard configuration	Compatible with transmitter frequency Universal design for behind-the-ear (BTE) hearing aids or cochlear implants with DAI
3. Receiver with an induction neck loop	
	
Typical user	Child or adult with a compatible hearing aid or cochlear implant
Specific characteristics	Worn around the neck of the user of a hearing aid or cochlear implant
Requirements for standard configuration	Compatible with transmitter frequency for hearing aids or cochlear implants with T-coil Loop design with breakaway capabilities
<p>General design requirements</p> <p>The system should be lightweight, small, wearable, and user-friendly. It should be robust and appropriate for use by people of all age groups. The system should operate within regionally authorized frequency bands for the FM system or 2.4–2.5 GHz frequency bands as specified in the industrial, scientific, and medical (ISM) radio bands for the DM system. The FM system should be designed to achieve high frequency (HF) characteristics SNR > 45 db.</p>	
<p>Standards</p> <p>Standards for wireless communication technologies for potential hazardous effects associated with electromagnetic (non-ionizing) radiation interaction with human tissue.</p> <p>IEC 62209–2 Ed. 1.0 Human Exposure to Radiofrequency Fields from Handheld and Body-mounted Wireless Communications Devices – Human Models, Instrumentation and Procedures: Procedure to Determine the Specific Absorption Rate for Wireless Communication Devices Used in Close Proximity to the Human Body (Frequency Range of 3 MHz to 6 GHz). Electromagnetic compatibility (EMC) and electrical safety assessments for all electronic equipment including medical devices</p> <p>IEC 60601–1 Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance (several parts may apply)</p> <p>ETSI EN 300 328 Wideband Transmission Systems</p>	
<p>Environment of use</p> <p>The product should function in an ambient temperature range of –20 to +45 °C and relative humidity range of 0% to 80% (6).</p>	
<p>Accessories and spare parts</p> <p>The following accessories should be required:</p> <ul style="list-style-type: none"> • transmitters and receiver(s) storage containers. <p>The following spare parts should be required:</p> <ul style="list-style-type: none"> • external microphones • batteries • audio shoes for universal receivers. 	

Other product requirement

The following additional information should be required:

- operating frequency
- battery life for typical use

Hearing aids

Name of product

Hearing aids (digital) and batteries

ISO 9999 code

22 06 15 Behind-the-ear hearing aids

22 06 27 Accessories for assistive products for hearing

Description and intended use.

Hearing aids are electronic devices attached to the ear that amplify sound and direct that sound into the ear. They are intended to assist children and adults who experience varying degrees of hearing loss, from deaf to hard of hearing, in the perception of environmental sounds and to hear and understand oral language.

General Features

A hearing aid typically incorporates a microphone(s), receiver, amplification unit and power supply and works with an ear coupling system such as tubing (standard or slim) and an earmould or ear insert. It is powered by conventional or rechargeable batteries inside the device. Hearing aids vary in power and pattern of amplification depending on the degree, configuration and type of hearing loss. Hearing aids may include compatibility with additional features such as telecoils (T-coils), directional microphones and direct audio input (DAI) to assist hearing in unique situations.

Inclusion

Behind-the-ear hearing aids with preconfigured ear inserts or custom earmoulds
Preprogramed behind-the-ear hearing aids

Exclusion

Analogue hearing aids
In-the-ear, spectacle, and body-worn hearing aids
Bone conduction hearing aids
Other assistive listening or amplification devices
Cochlear implant processors

Keywords



Communication, DAI, deaf, hard of hearing, hearing loss, preprogramed, T-coil

Functional requirements

1. Behind-the-ear hearing aid with preconfigured ear inserts

**Typical user**




Child or adult with mild to profound hearing loss in most environments

Specific characteristics	Meets amplification needs of users with specific hearing loss configurations in mild to profound range Device may incorporate controls or interfaces that allow it to be programmed to meet individual amplification needs
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meet requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) Coupling system for custom-made earmoulds
2. Behind-the-ear hearing aid with custom earmoulds	
	
Typical user	Child or adult with mild to profound hearing loss in most environments
Specific characteristics	Meets amplification needs of users with specific hearing loss configurations in mild to profound range Device may incorporate controls or interfaces that allow it to be programmed to meet individual amplification needs
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meet requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) Coupling system for custom-made earmoulds
3. Preprogrammed behind-the-ear hearing aid with either custom earmoulds or preconfigured ear inserts	
	
Typical user	Adults with targeted common hearing loss configurations
Specific characteristics	Meets generic amplification needs of targeted hearing loss configurations in mild to severe range Device incorporates controls or interface that allows selection of hearing program
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meets requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) At least three preset hearing programmes Preconfigured (stock or disposable) ear inserts in a variety of sizes or custom-made earmoulds

<p>General design requirements</p> <p>The frame of the reading glasses should be durable and lightweight. The lens should be impact- and scratch resistant. The lens diameter should depend on the lens design and frame size.</p>
<p>Standards</p> <p>IEC 60118 Electroacoustics – Hearing Aids (several parts in this series may be applicable)</p>
<p>Environment of use</p> <p>Hearing aids should be able to withstand various weather conditions, including light rain, snow and dust. Hearing aids need to function in an ambient temperature range of –20 to +45 °C and a relative humidity range of 0% to 80%</p>
<p>Accessories and spare parts</p> <p>The following accessories are required:</p> <ul style="list-style-type: none"> • hearing-aid storage containers for users • hearing-aid cleaning tools (e.g. small brushes and wires); • batteries.
<p>Other product requirements</p> <p>Battery life for typical use should be specified.</p>

3.4 Cognitive

<p>Communication boards and books</p>
<p>Name of product</p> <p>Communication boards, books, and cards</p>
<p>ISO 9999 code</p> <p>22 21 03 Letter and symbol sets and boards</p>
<p>Description and intended use.</p> <p>Communication boards and books enable the user to communicate using symbols, words, pictures, or objects. The user looks at, points to, or otherwise selects items on the communication board or book. The communication board or book adds to or replaces spoken communication. Communication boards and books are intended for use by children and adults with limited or no spoken communication, such as due to a neurological problem, hearing loss or intellectual disability.</p>
<p>General Features</p> <p>Communication boards are printed boards incorporating a grid of communication resources such as a set of symbols, paintings, icons, real-life pictures, letters, words or objects to represent ideas when communicating with others. Communication boards or books are made from durable materials or laminated paper or card. They can be fixed to a shelf, wheelchair tray, table or wall. Communication boards and books can be designed and printed using dedicated computer software.</p>
<p>Inclusion</p>

<p>Universal communication boards (multi-layer static communication boards) Customized (personalized) communication boards Eye-pointing communication frames Communication books</p>	
<p>Exclusion</p> <p>Products designed as visual infographics or schedules primarily for organization and management/ marketing rather than communication Therapy aids for speech or language using printed boards for training, therapy, and intervention but not communication</p>	
<p>Keywords</p> <p>Communication symbol, eye-pointing, multi-layer static communication board</p>	
<p>Functional requirements</p>	
<p>1. Universal communication board</p>	
	
<p>Typical user</p>	<p>Child or adult with limited or no spoken communication and who has complex communication needs</p>
<p>Specific characteristics</p>	<p>Communication symbols and board layouts produced in accordance with common standards or user's needs</p>
<p>Requirements for standard configuration</p>	<p>Vocabulary can be varied to reflect user's needs and culture</p>
<p>2. Customized (personalized) communication board</p>	
	
<p>Typical user</p>	<p>Child or adult with limited or no spoken communication and who wants to build on and extend the vocabulary of the universal communication board</p>
<p>Specific characteristics</p>	<p>Communication symbols and board layouts reflect user's needs</p>
<p>Requirements for standard configuration</p>	<p>In addition to following the general principles of communication board design, specific communication symbols or usage methods can be set according to user's needs</p>
<p>3. Eye-pointing communication frame</p>	
	

Typical user	Child or adult with limited or no spoken communication and with severely restricted limb movement, relying on the eye to look at symbols to communicate
Specific characteristics	Symbols and words from available range are attached around a frame, which is held vertically during communication
Requirements for standard configuration	The frame is usually rectangular with a gap in the middle where communication partners can see each other Symbols and words are attached around the frame in a consistent format so they can be easily found and pointed at by the eye

4. Communication book



Typical user	Child or adult with limited or no spoken communication and who uses a wider vocabulary
Specific characteristics	Collection of symbols related to a common theme or setting is displayed as individual pages reflecting interests.
Requirements for standard configuration	According to users' communication needs, pages are produced in different categories and bound into a book.

General design requirements
The communication board or book should be easy to carry and suitable for use. The materials must be appropriate and safe (e.g., non-toxic laminate) and can protect the board or book from damage. The print should be clear and easy to read, with good contrast, and use permanent ink. Software for designing and printing the board or book should be available on CD or through direct download; the availability of backup media should be identified. The grid and symbol layout should be adjustable with the software.


Standards
Board size: ISO 19027:2016(E)3.1a
Board materials (paper or plastic): ISO 19027:2016(E)3.1b
Design of the symbol on the board: ISO 19027:2016(E)3.2
Layout of display item on board: ISO 19027:2016(E)3.2
Clarity and contrast of print: ISO 19027:2016(E)3.2




Environment of use
The product should withstand heat, dust, humid and dry environments.

Lifespan
The product should have a lifespan of at least three years

Other product requirements
Information on tactile printers and their compatibility with tactile symbols should be provided. Information on whether both color and black-and-white versions of symbols should be used on the board should be provided

3.5 Self Care

Commode chairs	
Name of product Chairs for shower/bath/toilet	
ISO 9999 code 09 12 03 Commode chairs 09 12 12 Raised toilet seats mounted on a frame. 09 33 07 Shower chairs with and without wheels	
Description and intended use. Toilet and shower chairs provide solutions for children and adults who find it difficult or impossible to use a standard toilet or shower. Users may need support to transfer on or off the chair and when washing and drying themselves.	
General Features A toilet or shower chair comprises a chair or stool with a seat and is either static or mobile with wheels or castors. It may have armrests or footrests.	
Inclusion Static toilet or shower chairs or stools Mobile shower commode chairs Foldable mobile shower commode chairs	
Exclusion Tub transfer benches Bathtub seats/benches Toilet seats and seat inserts	
Keywords Commode, commode chair with wheels, over-toilet shower commode, shower chair, toilet wheelchair	
Functional requirements	
1. Static toilet chair	
	
Typical user	Child or adult who cannot access or safely use their existing toilet
Specific characteristics	Static chair with a backrest that can be placed over toilet or used away from toilet with a removable collection bucket
Requirements for standard configuration	Fixed or removable backrest Seat with aperture Removable collection bucket (pan) Height-adjustable legs fitted with non-slip tips; minimum height should be sufficient to clear the toilet it will be placed over (for pedestal toilet) Sizes to fit children and adults. Bariatric range for users over 120 kg May include toilet splash guard and fixed or removable armrests
2. Static shower stool	

	
Typical user	Child or adult unable to stand safely or at all to wash themselves, but with good sitting balance
Specific characteristics	Static stool without backrest
Requirements for standard configuration	<p>Complete seat or with aperture</p> <p>Height-adjustable legs fitted with non-slip tips.</p> <p>Sizes to fit children and adults.</p> <p>Bariatric range for users over 120 kg</p> <p>May include fixed or removable armrests</p>
3. Static shower chair	
	
Typical user	Child or adult unable to stand safely or at all to wash themselves, and who needs backrest support to sit safely
Specific characteristics	Static chair with backrest
Requirements for standard configuration	<p>Fixed backrest</p> <p>Complete seat or with aperture</p> <p>Height-adjustable legs fitted with non-slip tips.</p> <p>Sizes to fit children and adults.</p> <p>Bariatric range for users over 120 kg</p> <p>May include fixed or removable armrests</p>
4. Attendant-propelled mobile toilet and shower chair	
	
Typical user	Child or adult who cannot access or safely use their existing toilet and wash area; who requires assistance with transferring and mobility; and who prefers to move in their shower or toilet chair to access wash areas
Specific characteristics	Chair with backrest and wheels to be pushed by a carer

Requirements for standard configuration	<p>Fixed backrest with push-handles</p> <p>Seat with aperture</p> <p>Removable collection bucket (pan)</p> <p>Removable armrests</p> <p>Height-adjustable, flip-up or removable footrests</p> <p>Four swivel castors (at least two lockable); or two rear wheels and two front. castors</p> <p>Sizes to fit children and adults.</p> <p>Bariatric range for users over 120 kg</p> <p>May include commode with tilt-in-space option (minimum 0–35 °); heightadjustable headrest; or pelvis or trunk straps and supports</p>
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5. Self-propelled mobile toilet and shower chair



Typical user	Child or adult who cannot access or safely use their existing toilet and wash area; but who is able to and prefers to self-propel in their shower or toilet chair to access wash areas
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Specific characteristics	Chair with backrest and large rear wheels to be propelled by the user
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Requirements for standard configuration	<p>Fixed backrest with push-handles</p> <p>Seat with aperture</p> <p>Removable collection receptacle (pan)</p> <p>Removable armrests</p> <p>Height-adjustable, flip-up or removable footrests</p> <p>Two rear wheels with brakes and two front castors</p> <p>Sizes to fit children and adults.</p> <p>Bariatric range for users over 120 kg</p> <p>May include commode with tilt-in-space option (minimum 0–35 °); heightadjustable headrest; or pelvis or trunk straps and supports</p>
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6. Folding toilet or shower commode chair



Typical user	Child or adult who cannot access or safely use existing toilet and wash areas; who needs backrest support; and who needs a folding chair either to save space or to allow for travel with the device
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Specific characteristics	<p>Lightweight chair for toilet and shower</p> <p>Can be folded for transportation</p>
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Requirements for standard configuration	<p>Chair with folding or collapsible frame</p> <p>Chair with backrest and push-handles</p> <p>Seat with aperture</p> <p>Removable collection receptacle (pan)</p> <p>Removable armrests</p> <p>Height-adjustable, flip-up or removable footrests</p> <p>Two large rear wheels with brakes for self-propelling and two front castors</p> <p>Sizes to fit children and adults.</p> <p>Bariatric range for users over 120 kg</p>
<p>General design requirements</p> <p>The chair or stool should be made from a material that is rustproof, waterproof and contamination resistant, and with a smooth finish to enable easy cleaning and to prevent injury to the bare skin. Each product should have sufficient strength and durability for daily sustained use. Tips, castors and wheels must be replaceable.</p> <p>For self-propelled chairs, the large rear wheels need to be in an optimal position for the user to reach.</p>	
<p>Standards</p> <p>ISO 17966:2016 Assistive Products for Personal Hygiene that Support Users – Requirements and Test Methods</p>	
<p>Size and weight</p> <p>Information about overall width, width between arms, seat dimension, floor-to-seat height, weight of chair, and safe working load and product capacity of the chair should be provided.</p> <p>If applicable, dimensions in operating and folded modes should be provided.</p> <p>Where applicable, height-adjustment ranges should be provided</p>	
<p>Environment of use</p> <p>The product should withstand conditions in a domestic bathroom, such as warm water and humidity.</p>	
<p>Accessories and spare parts</p> <p>The following accessories should be procured if not automatically provided with the product:</p> <ul style="list-style-type: none"> • seats • removable buckets • splash guards. 	

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