



Assistive products for persons with disability—General requirements and test methods

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- Assistive Technology Suppliers Australasia
 - Association of Consultants in Access Australia
 - Australian Rehabilitation and Assistive Technology Association
 - Bus and Coach Association of New Zealand
 - Commercial Vehicle Industry Association of Australia
 - Consumers Federation of Australia
 - Department of Family and Communities, SA
 - Engineers Australia
 - Independent Living Centres Australia
 - Medical Aids Subsidy Scheme (MASS)
 - New Zealand Transport Agency
 - Novita Children's Services
 - Occupational Therapy Australia
 - Physical Disability Australia
 - Queensland Health
 - Royal Perth Hospital
 - TAD Australia
 - Therapeutic Goods Administration
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Australian Standard[®]

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disability—General requirements and
test methods**

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PREFACE

This Standard was prepared by the Standards Australia Committee ME-067, Assistive products for persons with disability—General requirements and test methods.

The objective of this Standard is to specify requirements and test methods for assistive products for persons with disability.

This Standard is identical with, and has been reproduced from EN 12182:2012, *Assistive products for persons with disability—General requirements and test methods*.

As this Standard is reproduced from a European Standard, the following applies:

- (a) In the source text ‘this European Standard’ should read ‘this Australian Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
EN	AS EN
556 Sterilization of medical devices— Requirements for medical devices to be designated “STERILE”	556 Sterilization of medical devices— Requirements for medical devices to be designated “STERILE”
556-1 Part 1: Requirements for terminally sterilized medical devices	556.1 Part 1: Requirements for terminally sterilized medical devices
EN ISO	AS/NZS ISO
11137 Sterilization of health care products— Radiation	11137 Sterilization of health care products— Radiation
11137-1 Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1 Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
11137-2 Part 2: Establishing the sterilization dose	11137.2 Part 2: Establishing the sterilization dose
13850 Safety of machinery—Emergency stop—Principles for design	AS/NZS 4024 Safety of machinery 4024.1604 Part 1604: Design of controls, interlocks and guarding—Emergency stop—Principles for design
CISPR	AS/NZS CISPR
11 Industrial, scientific and medical equipment—Radio-frequency disturbance characteristics—Limits and methods of measurement	11 Industrial, scientific and medical equipment—Radio-frequency disturbance characteristics—Limits and methods of measurement

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

CONTENTS

1	Scope	7
2	Normative references	7
3	Terms and definitions	9
4	General requirements.....	11
4.1	Risk analysis	11
4.2	Intended performance and technical documentation.....	11
4.3	Clinical evaluation and investigation.....	12
4.4	Assistive products that can be dismantled	12
4.5	Fasteners	12
4.6	Mass limits.....	12
4.7	Immobilising means	12
4.8	Design requirements in relation to persons with cognitive impairment.....	12
5	Materials	13
5.1	General.....	13
5.2	Flammability	13
5.2.1	General.....	13
5.2.2	Upholstered parts, mattresses, bed bases and bedding.....	13
5.2.3	Upholstered parts	13
5.2.4	Mattresses and bed bases	13
5.2.5	Bedding.....	14
5.2.6	Moulded parts	14
5.3	Biocompatibility and toxicity.....	14
5.4	Contaminants and residues.....	14
5.4.1	General.....	14
5.4.2	Substances which may leak from an assistive product in intended use and in fault conditions.....	14
5.5	Infection and microbiological contamination	15
5.5.1	Cleaning and disinfection	15
5.5.2	Animal tissue.....	15
5.6	Resistance to corrosion.....	15
6	Emitted sound and vibration	15
6.1	Noise and vibration.....	15
6.2	Sound levels and frequencies of audible warning devices.....	15
6.3	Feedback	16
7	Electromagnetic compatibility.....	16
7.1	General.....	16
7.2	Emissions	16
7.3	Immunity	16
7.4	Power frequency magnetic field immunity	16
8	Electrical safety.....	17
8.1	General.....	17
8.2	Electrical systems.....	17
8.3	Continuity of power supply	17
8.4	Battery powered assistive products	18
8.4.1	Battery housings.....	18
8.4.2	Connection	18
8.4.3	Charge level indicator	18
8.5	Circuit protection	19
8.6	Electronic programmable systems.....	20
8.7	Electrically heated blankets, pads and similar flexible heating appliances.....	20

8.8	Assistive products with skin contact electrodes	20
8.9	Ingress of liquids	20
9	Overflow, spillage, leakage, and ingress of liquids	21
9.1	Overflow	21
9.1.1	Requirements	21
9.1.2	Test method	21
9.2	Spillage	21
9.2.1	Requirements	21
9.2.2	Test method	21
9.3	Leakage	21
9.4	Ingress of liquids	21
9.4.1	Requirements	21
9.4.2	Test method	22
10	Surface temperature	22
11	Sterility	22
11.1	Sterility requirements	22
11.2	Sterilization processes	22
11.3	Maintenance of sterility in transit	23
12	Safety of moving parts	23
12.1	Squeezing	23
12.2	Mechanical wear	23
12.3	Emergency stopping functions	24
13	Prevention of traps for parts of the human body	24
13.1	Holes and clearances	24
13.2	V-shaped openings	25
14	Folding and adjusting mechanisms	25
14.1	General	25
14.2	Locking mechanisms	25
14.3	Guards	25
15	Carrying handles	25
15.1	General	25
15.2	Requirement	26
15.3	Test method	26
16	Assistive products which support or suspend users	26
16.1	General	26
16.2	Static forces	27
16.3	Dynamic forces	27
16.4	Requirements and test method for tips	27
16.4.1	General	27
16.4.2	Friction of tips	27
16.4.3	Durability of tips	27
17	Portable and mobile assistive products	27
18	Surfaces, corners, edges and protruding parts	29
19	Hand held assistive products	29
20	Small parts	29
21	Stability	29
22	Forces in soft tissues of the human body	29
23	Ergonomic principles	29
24	Requirements for information supplied by the manufacturer	30
24.1	General	30
24.2	Instructions for use	31
24.2.1	Pre-sale information	31
24.2.2	User information	31

24.2.3	Service information	32
24.3	Labelling	32
25	Packaging	33
26	Test report	33
Annex A	(informative) European standards for assistive products for persons with a disability produced or currently being developed by CEN/TC 293	34
Annex B	(informative) General recommendations.....	36
Annex C	(informative) Cognitive impairment	43
Annex D	(informative) Environmental and consumer related requirements.....	50
Annex ZA	(informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	56
	Bibliography	61

AUSTRALIAN STANDARD

Assistive products for persons with disability—General requirements and test methods**1 Scope**

This European Standard specifies general requirements and test methods for assistive products for persons with a disability, which are medical devices according to the definition laid down in the EU Directive 93/42/EEC.

This European Standard does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

Where other European Standards exist for particular types of assistive products then those standards apply. However, some of the requirements of this standard may still apply and may be considered in addition to those in other European standards.

NOTE Not all the items listed in EN ISO 9999 are medical devices. Contracting parties may wish to consider if this standard or parts of this standard can be used for assistive products which are not medical devices as defined in the EU Directive 93/42/EEC.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source: Smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: Match flame equivalent*

EN 614-1, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1021-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

EN 1021-2, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN ISO 25424, *Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424)*

EN 60065, *Audio, video and similar electronic apparatus — Safety requirements (IEC 60065)*

EN 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1)*

EN 60529, *Degrees of protection provided by enclosures (IP Code) (IEC 60529)*

EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*