Australian STANDARD

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

STANDARDS Australia

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The following are represented on Committee ME-067:

- Assistive Technology Suppliers Australasia
- Association of Consultants in Access Australia
- Australian Rehabilitation an 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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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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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:

Reference to International Standard		*Australian/New Zealand Standard*	
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.

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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 labeling 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)*

