AS EN 12182—2002
EN 12182:1999

Australian Standard™

Technical aids for disabled persons—General requirements and test methods

Standards Australia

This Australian Standard was prepared by Committee ME-067, Mobility Appliances for People with Disabilities. It was approved on behalf of the Council of Standards Australia on 25 June 2002 and published on 18 July 2002.

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Australian Association of Occupational Therapists

Australian Chamber of Commerce and Industry

Australian Committee of Independent Living Centres

Australian Industry Group

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Technical Aid to the Disabled

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PREFACE

This Standard was prepared by Australian members of the Joint Standards Australia/Standards New Zealand Committee ME-067, Mobility Appliances for People with Disabilities to be used as a means to demonstrate compliance with the relevant essential principles in new medical device legislation.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from EN 12182:1999, *Technical aids for disabled persons — General requirements and test methods.*

The objective of this Standard is to specify general requirements and test methods for technical aids for disabled persons which are intended by the manufacturer to be medical devices.

This Standard provides for the use of Australian/New Zealand Standards as equivalents to particular CEN Standards referenced herein, as follows:

Reference to European Standard		*Australian/New Zealand Standard*	
EN		AS/NZS ISO	
60335	Safety of household and similar electrical appliances	3350	Safety of household and similar electrical appliances
60335-1	Part 1: General requirements	3350.1	Part 1: General requirements (IEC 60335-1:1991, MOD)
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety — Parent Standard
60601-1-2	2. Collateral standard: Electromagnetic compatibility— Requirements and test methods	3200.1.2	Part 1.2: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests
60601-1-4	4. Collateral standard: Programmable electrical medical systems	3200.1.4	Part 1.4: General requirements for safety — Collateral Standard: Programmable electrical medical systems
61000	Electromagnetic compatibility (EMC)	61000	Electromagnetic compatibility (EMC)
61000-3-2	Part 3: Limits—Section 2: Limits for harmonic current emissions	61000.3.2	Part 3.2: Limits—Limits for harmonic current emissions (equipment input current less than or equal to 16 A per phase)
61000-3-3	Part 3: Limits—Section 3: Limitation of voltage fluctuations and flicker in low voltage systems for equipment with current up to 16 A	61000.3.3	Part 3.3: Limits—Limitation of voltage fluctuations and flicker in low-voltage systems for equipment with rated current less than or equal to 16 A
61000-4-3	Part 4: Testing and measurement techniques—Section 3: Radiated, radio-frequency, electromagnetic field immunity	61000.4.3	Part 4.3: Testing and measurement techniques—Radiated, radio-frequency, electromagnetic field immunity test

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

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text 'this European Standard' should read 'this Australian Standard'.

(c) A full point substitutes for a comma when referring to a decimal marker.

For the purposes of this Standard, the CEN Annex regarding the fulfilment of European Council Directives has been removed.

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AUSTRALIAN STANDARD

Technical aids for disabled persons—General requirements and test methods

1 Scope

This European Standard specifies general requirements and test methods for technical aids for disabled persons which are intended by the manufacturer to be medical devices for the purposes of EU Directive 93/42/EEC concerning medical devices.

This standard does not apply to technical aids which achieve their intended purpose by administering pharmaceutical substances to the user.

Where other European Standards exist for particular types of technical aids then those standards apply. However, some of the requirements of this standard may still apply and may be specified in those other European standards

NOTE: Not all the items listed in EN ISO 9999:1998 are medical devices. Contracting parties may wish to consider if this standard, or parts of this standard can be used to specify aids which are not medical devices as defined in the EU Directive 93/42/EEC.

2 Normative references

This European Standard incorporates by dated or undated reference, provision from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 418	Safety of machinery. Emergency stop equipment, functional aspects - Principles for design
EN 540:1993	Clinical investigations of medical devices for human subjects
EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization.
EN 552	Sterilization of medical devices - Validation and routine control of sterilization by irradiation.
EN 554	Sterilization of medical devices - Validation and routine control of steam sterilization by moist heat.
EN 556	Sterilization of Medical Devices - Sterility Assurance Level for Medical Devices labelled