AS/NZS IEC 60601.1:2015
IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV
(Incorporating Amendment No. 1)

Australian/New Zealand Standard™

Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

AS/NZS IEC 60601.1:2015

This Joint Australian/New Zealand Standard™ was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 August 2015 and by the Council of Standards New Zealand on 21 August 2015.

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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
Ministry of Business, Innovation and Employment, New Zealand
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration
Wairarapa District Health Board
Waitemata District Health Board

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.1.0:1998 *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard*.

〈A1〉*Amendment No. 1 (June 2022) to this Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment.*〈A1〉

The objective of this Standard is to specify general requirements for basic safety and essential performance of medical electrical equipment and medical electrical systems. This is applicable to a subgroup of medical electrical equipment (e.g. radiological equipment) and a specific characteristic of all medical electrical equipment not fully addressed in this Standard.

〈A1〉This Standard is identical with, and has been reproduced from, IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV (ED. 3.2), *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*, which incorporates its Corrigendum 1 (2006), Corrigendum 2 (2007), Amendment 1 (2012) and Amendment 2 (2020).〈A1〉

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text "this International Standard" should read "this Australian/New Zealand 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*	
IEC		AS/NZS	
60079	Explosive atmospheres	60079	Explosive atmospheres
60079-0	Part 0: Equipment—General requirements	60079.0	Part 0: Equipment—General requirements
60335	Household and similar electrical appliances—Safety	60335	Household and similar electrical appliances—Safety
60335-1	Part 1: General requirements	60335.1	Part 1: General requirements (IEC 60335-1 Ed.5, MOD)
		AS	
60529	Degrees of protection provided by enclosures (IP Code)	60529	Degrees of protection provided by enclosures (IP Code)
		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1-8	Part 1-8: General requirements for basic safety and essential performance—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	3200.1.8	Part 1.8: General requirements for safety—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

		AS/NZS IEC	
60825	Safety of laser products	60825	Safety of laser products
60825-1	Part 1: Equipment classification and requirements	60825.1	Part 1: Equipment classification and requirements
IEC		AS/NZS	
60884	Plugs and socket-outlets for household and similar purposes	60884	Plugs and socket-outlets for household and similar purposes
60884-1	Part 1: General requirements	60884.1	Part 1: General requirements (IEC 60884-1, Ed. 3.1 (2006) MOD)
60950	Information technology equipment—Safety	60950	Information technology equipment—Safety
60950-1	Part 1: General requirements	60950.1	Part 1: General requirements (IEC 60950-1, Ed. 2.0 (2005) MOD)
61058	Switches for appliances	61058	Switches for appliances
61058-1	Part 1: General requirements	61058.1	Part 1: General requirements (IEC 61058-1, Ed. 3.1 (2000) MOD)
ISO		AS	
780	Packaging—Pictorial marking for handling of goods	2852	Packaging—Pictorial marking for the handling of packages
		AS ISO	
5349	Mechanical vibration—Measurement and evaluation of human exposure to hand-transmitted vibration	5349	Mechanical vibration—Measurement and evaluation of human exposure to hand-transmitted vibration
5349-1	Part 1: General requirements	5349.1	Part 1: General requirements
10993	Biological evaluation of medical devices	10993	Biological evaluation of medical devices
10993-4	Part 4: Selection of tests for interactions with blood	10993.4	Part 4: Selection of tests for interactions with blood
10993-14	Part 14: Identification and quantification of degradation products from ceramics	10993.14	Part 14: Identification and quantification of degradation products from ceramics
10993-15	Part 15: Identification and quantification of degradation products from metals and alloys	10993.15	Part 15: Identification and quantification of degradation products from metals and alloys
10993-17	Part 17: Establishment of allowable limits for leachable substances	10993.17	Part 17: Establishment of allowable limits for leachable substances
		AS/NZS ISO	