

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

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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
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This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.1:2015.

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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**

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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
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