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AS IEC 60601.2.22:2014
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Australian STANDARD

Medical electrical equipment

Part 2.22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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This Australian Standard® was prepared by Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 10 September 2014.
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The following are represented on Committee HE-003:

- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Dental Association
- Australian Society of Anaesthetists
- College of Biomedical Engineering Engineers Australia
- Department of Defence (Australia)
- Medical Technology Association of Australia
- Testing and Certification Interests
- Therapeutic Goods Administration

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Australian Standard®

Medical electrical equipment

Part 2.22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

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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 3200.2.22:1997, *Medical electrical equipment*, Part 2-22: *Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*.

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

The objective of this Standard is to set out requirements for the basic safety and essential performance of laser equipment for surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended use on humans or animals, classified as a Class 3B or Class 4 laser product as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as laser equipment.

This Standard is identical with, and has been reproduced from IEC 60601-2-22:2012, *Medical electrical equipment*, Part 2-22: *Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*.

This Document is the consolidated version of IEC 60601-2-22, which consists of the third edition (2007) and its amendment 1 (2012). The technical content is identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

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 Standard*	
IEC		AS/NZS	
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
60947	Low-voltage switchgear and controlgear	3947	Low-voltage switchgear and controlgear
60947-3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	3947.3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units
61010	Safety requirements for electrical equipment for measurement, control and laboratory use	61010	Safety requirements for electrical equipment for measurement, control and laboratory use

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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