

Australian Standard™

**Dentistry—Medical devices for  
dentistry—Equipment**

This Australian Standard was prepared by Committee HE-004, Dental Products and Equipment. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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The following are represented on Committee HE-004:

Australian Chamber of Commerce and Industry  
Australian Dental Association  
Australian Dental Industry Association Inc  
Commonwealth Department of Health and Ageing  
Department of Defence (Australia)  
The University of Melbourne

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**Dentistry— Medical devices for  
dentistry— Equipment**

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## PREFACE

This Standard has been developed to assist in the process of implementation of the Australian 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, through the Joint Standards Australia/Standards New Zealand Committee HE-004 on Dental Products and Equipment.

This Standard is identical with and has been reproduced from EN 1640:1996, *Dentistry — Medical devices for dentistry — Equipment*.

The objective of this Standard is to specify requirements for items of dental equipment used in the practice of dentistry and which are medical devices. These include requirements for intended performance, design attributes, components, packaging, marking, labelling and information supplied by the manufacturer.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the International Standards referenced herein:

*Reference to International Standard or other Equivalent Australian/New Zealand Standard publication*

IEC	AS/NZS
60601-1 Medical electrical equipment – Part 1: General requirements for safety	3200.1.0 Medical electrical equipment – Part 1.0: General requirements for safety – Parent Standard

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

- Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- In the source text 'this European Standard' should read 'this Australian Standard'.
- A full point substitutes for a comma when referring to a decimal marker.

## AUSTRALIAN STANDARD

**Dentistry—Medical devices for dentistry—Equipment****1 Scope**

This European Standard specifies general requirements for items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer.

This standard does not include requirements for dental X-ray equipment.

This standard does not apply to any dental instruments connected to an item of dental equipment. These instruments are covered by the level 2 and level 3 standards for dental instruments.

Tests for demonstrating compliance with this standard are contained in the level 3 standards, if appropriate.

**2 Normative references**

This European Standard incorporates by dated or undated references provisions 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 980	Graphical symbols for use in the labelling of medical devices
prEN 1041	Information supplied by the manufacturer with medical devices
EN 1639	Dentistry - Medical devices for dentistry - Instruments
EN 21942-1	Dental vocabulary - Part 1: General and clinical terms
EN 21942-4	Dental vocabulary - Part 4: Dental equipment
EN 18661	Data elements and interchange formats - Information interchange - Representation of dates and times
EN 50601-1	Medical electrical equipment - Part 1: General requirements for safety