AS EN 1641—2002
EN 1641:1996

Australian Standard™

Dentistry—Medical devices for dentistry—Materials

Standards Australia

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.

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— Materials

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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 1641:1996, *Dentistry — Medical devices for dentistry — Materials*.

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

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.

AUSTRALIAN STANDARD

Dentistry—Medical devices for dentistry—Materials

1 Scope

This European Standard specifies general requirements for materials used in the practice of dentistry for the restoration of the form and function of the dentition and which are medical devices. For the purposes of this standard these materials are defined as restorative materials. Dental implants are specifically excluded and described in EN 1642. This standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

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 reference 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 540	Clinical investigation of medical devices for human subjects
EN 980	Graphical symbols for use in the labelling of medical devices
prEN 1041	Information supplied by the manufacturer with medical devices
EN 1642	Dentistry - Medical devices for dentistry - Dental implants
EN 21942-1	Dental vocabulary - Part 1: General and clinical terms
EN 21942-2	Dental vocabulary - Part 2: Dental materials
EN 21559	Dentistry - Alloys for dental amalgam
EN 21560	Dentistry - Dental mercury
EN 21561	Dental inlay casting wax
EN 21563	Dental alginate impression material
EN 21564	Dentistry - Agar impression material
EN 23107	Dental zinc oxide/eugenol cements and zinc oxide non-eugenol cements
EN 24049	Dentistry - Resin-based filling materials