AS EN 1642—2002
EN 1642:1996

Australian Standard™

Dentistry—Medical devices for dentistry—Dental implants

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— Dental implants

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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 1642:1996, *Dentistry — Medical devices for dentistry — Dental implants*.

The objective of this Standard is to specify requirements for dental implants, including 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—Dental implants

1 Scope

This European Standard specifies general requirements for dental implants. Surgically implantable dental materials defined as restorative materials are specifically excluded and described in EN 1641. This Standard includes requirements for intended performance, design attributes, components, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

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 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization
EN 552	Sterilization of medical devices - Validation and routine control of sterilization on by irradiation
EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
EN 980	Graphical symbols for use in the labelling of medical devices
prEN 1041	Information supplied by the manufacturer with medical devices
EN 1641	Dentistry - Medical devices for dentistry - Materials
EN 21942-1	Dental vocabulary - Part 1: General clinical terms
EN 21942-2	Dental vocabulary - Part 2: Dental materials
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times
EN 30993-1	Biological evaluation of medical devices - Part 1: Guidance on selection of tests
EN 30993-3	Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity
EN 30993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN 30993-5	Biological evaluation of medical devices - Part 5: Tests for cytotoxicity - In vitro methods
EN 30993-6	Biological evaluation of medical devices - Part 6: Test for local effects after implantation