

Dentistry — Medical devices for dentistry — Dental implants

ICS 11.060.15

National foreword

This British Standard is the UK implementation of EN 1642:2009. It supersedes BS EN 1642:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/8, Dental implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Implants dentaires

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde -
Dentalimplantate

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Foreword

This document (EN 1642:2009) has been prepared by Technical Committee CEN/TC 55 “Dentistry”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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This document supersedes EN 1642:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

For relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

The following changes were made:

a) Normative references:

- 1) Addition of new relevant product standards, issued after 2004: EN 1641, EN ISO 11135-1, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14801, EN ISO 14971, EN ISO 22794, EN ISO 22803;
- 2) Deletion of the following withdrawn standards: EN 550, EN 552, EN ISO 14727;

b) 4.5 Clinical evaluation: Clarification of requirement for a clinical evaluation;

c) 4.6.4 Instructions for use: Clarification of requirement that information may be provided in an electronic format;

d) Annex ZA: Actualisation of correspondence between this European Standard and Directive 93/42/EEC, as amended by Directive 2007/47/EC.

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