Irish Standard
I.S. EN 1642:2011

Dentistry - Medical devices for dentistry - Dental implants

I.S. EN 1642:2011

Incorporating amendments/corrigenda/National Annexes issued since publication:

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English Version

Dentistry - Medical devices for dentistry - Dental implants

Médicine bucco-dentaire - Dispositifs médicaux pour la médicine bucco-dentaire - Implants dentaires

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Dentalimplantate

This European Standard was approved by CEN on 20 September 2011.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Contents

Foreword

This document (EN 1642:2011) 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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1642:2009.

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 the annex.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

There are three levels of European Standards dealing with medical devices used in dentistry. These are as follows:

— Level 1: General requirements for medical devices;

— Level 2: Requirements for families of medical devices used in dentistry;

— Level 3: Specific requirements for types of medical devices used in dentistry.

There are no level 1 standards written exclusively in respect of medical devices used in dentistry.

This European Standard is a level 2 standard and details requirements that apply to dental implants (for surgically implantable dental materials included within the definition of restorative materials see EN 1641). It is also indicated that there are additional requirements in the level 3 standards. Where available, these are included as normative references. To cover all the requirements for a particular product, it is necessary to use a standard of the lowest available level.

In the bibliography a reference for guidance on the classification of dental devices and accessories [4] is given.