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I.S. EN 1641:2009

Dentistry - Medical devices for dentistry - Materials

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English Version

Dentistry - Medical devices for dentistry - Materials

Art dentaire - Dispositifs médicaux pour l'art dentaire - Produits

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Werkstoffe

This European Standard was approved by CEN on 19 September 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

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 Management Centre has the same status as the official versions.

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Contents

Foreword

This document (EN 1641:2009) 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.

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 1641:2004.

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

For the 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) Addition of materials used in the practice of orthodontics;

b) Normative references:

    1) Addition of new relevant product standards, issued after 2004: EN ISO 3107, EN ISO 9333, EN ISO 9917-1, EN ISO 10139-1, EN ISO 14971, EN ISO 15841, EN ISO 15854, EN ISO 21606, EN ISO 22112, EN ISO 22674, EN ISO 24234.

    2) Deletion of the following withdrawn standards: EN 21560, EN 23107, EN 26874, EN 29333, EN 29917, EN 30139-1, EN ISO 1559, EN ISO 1561, EN ISO 1562, EN ISO 1567, EN ISO 3336, EN ISO 4824, EN ISO 6871-1, EN ISO 8891, EN ISO 12163.

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

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

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

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, 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 the 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 those materials used in the practice of dentistry for the restoration of the form and function of the dentition (for dental implants see EN 1642) and those for the practice of orthodontics. 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.

The manufacturer will need to consider whether:

1) The material incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EEC [2], and whose action in combination with the material can result in its bioavailability. Directive 2001/83/EEC specifies the appropriate methods for assessing the safety, quality and usefulness of that substance.

2) The material includes a constituent which may be classified as a hazardous substance according to the Dangerous Substances Directive 67/548/EEC [3], as amended by the Dangerous Preparations Directive 1999/45/EC [4]. Attention is drawn to the labelling requirements of these Directives where the hazardous constituent content is above certain concentration limits.

A reference for guidance on the classification of dental devices and accessories is given in the Bibliography [6].

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 and orthodontic materials. Dental implants are specifically excluded and described in EN 1642. This standard also specifies general requirements for materials used in the practice of orthodontics. 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

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 21563, *Alginate dental impression material (ISO 1563:1990)*

EN 21942-1:1991, *Dental vocabulary — Part 1: General and clinical terms (ISO 1942-1:1989)*

EN 21942-2:1992, *Dental vocabulary — Part 2: Dental materials (ISO 1942-2:1989)*

EN ISO 1564, *Dental aqueous impression materials based on agar (ISO 1564:1995)*

EN ISO 1942-5:1994, *Dental vocabulary — Part 5: Terms associated with testing (ISO 1942-5:1989)*

EN ISO 3107, *Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements (ISO 3107:2004)*

EN ISO 4049, *Dentistry — Polymer-based filling, restorative and luting materials (ISO 4049:2000)*

EN ISO 4823, *Dentistry — Elastomeric impression materials (ISO 4823:2000)*

EN ISO 6872, *Dentistry — Ceramic materials (ISO 6872:2008)*

EN ISO 6873, *Dental gypsum products (ISO 6873:1998)*

EN ISO 6874, *Dentistry — Polymer-based pit and fissure sealants (ISO 6874:2005)*

EN ISO 6876, *Dental root canal sealing materials (ISO 6876:2001)*

EN ISO 6877, *Dentistry — Root-canal obturating points (ISO 6877:2006)*

EN ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2008)*

EN ISO 7491, *Dental materials — Determination of colour stability (ISO 7491:2000)*

EN ISO 7551, *Dental absorbent points (ISO 7551:1996)*

EN ISO 9333, *Dentistry — Brazing materials (ISO 9333:2006)*

EN ISO 9693, *Metal-ceramic dental restorative systems (ISO 9693:1999)*

EN ISO 9917-1, *Dentistry — Water-based cements — Part 1: Powder/liquid acid-base cements (ISO 9917-1:2007)*