Irish Standard
I.S. EN 1639:2009

Dentistry - Medical devices for dentistry - Instruments

I.S. EN 1639:2009

Incorporating amendments/corrigenda issued since publication:

This document replaces:	*This document is based on:*	*Published:*
EN 1639:2004	EN 1639:2009 EN 1639:2004	28 October, 2009 6 August, 2004

This document was published
under the authority of the NSAI
and comes into effect on:
17 November, 2009

ICS number:
11.060.25

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I.S. EN 1639:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1639

October 2009

ICS 11.060.25

Supersedes EN 1639:2004

English Version

Dentistry - Medical devices for dentistry - Instruments

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

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Instrumente

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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Ref. No. EN 1639:2009: E

Contents

Foreword

This document (EN 1639:2009) 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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 1639:2004.

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(s).

For relationship with EU Directive(s), 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 13060, EN ISO 8325, EN ISO 11135-1, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14155-1, EN ISO 14155-2, EN ISO 14971, EN ISO 15883-1, EN ISO 17664, EN ISO 17665-1 and EN ISO 21571;

   2) Deletion of the following withdrawn standards: EN 550, EN 552, EN 554, EN 26360-2 and EN 28325.

b) 4.7 Clinical evaluation: Clarification of requirement for a clinical evaluation;

c) 4.10.6 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.

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 instruments used in the practice of dentistry. For instruments to be connected to an energy source, this European Standard should be used in conjunction with EN 1640, which is applicable for dental equipment. This European Standard also indicates 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 [3] is given.

1 Scope

This European Standard specifies general requirements for instruments used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, reprocessing, packaging, marking, labelling, and information supplied by the manufacturer.

This European Standard does not apply to any necessary energy source to which an instrument needs to be connected. These energy sources are covered by EN 1640.

Tests for demonstrating compliance with this European 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 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

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

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

EN 1640, *Dentistry — Medical devices for dentistry — Equipment*

EN 13060, *Small steam sterilizers*

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

EN 21942-3:1993, *Dental vocabulary — Part 3: Dental instruments (ISO 1942-3:1989)*

EN 23964, *Dentistry — Dental handpieces — Coupling dimensions (ISO 3964:1982)*

EN 29168, *Dental handpieces — Hose connectors (ISO 9168:1991)*

EN 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN ISO 1797-1, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals (ISO 1797-1:1992)*

EN ISO 1797-2, *Dental rotary equipment — Shanks — Part 2: Shanks made of plastics (ISO 1797-2:1992)*

EN ISO 2157, *Dental rotary instruments — Nominal diameters and designation code number (ISO 2157:1992)*

EN ISO 3630-1, *Dentistry — Root-canal instruments — Part 1: General requirements and test methods (ISO 3630-1:2008)*

EN ISO 3630-2, *Dental root-canal instruments — Part 2: Enlargers (ISO 3630-2:2000)*

EN ISO 3630-3, *Dental root-canal instruments — Part 3: Condensers, pluggers and spreaders (ISO 3630-3:1994)*

EN ISO 3823-1, *Dental rotary instruments — Burs — Part 1: Steel and carbide burs (ISO 3823-1:1997)*

EN ISO 3823-2, *Dentistry — Rotary bur instruments — Part 2: Finishing burs (ISO 3823-2:2003)*

EN ISO 7153-1, *Surgical instruments — Metallic materials — Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999)*