Stomatoloogia. Meditsiinivahendid stomatoloogias. Instrumendid

Dentistry - Medical devices for dentistry - Instruments

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 1639:2009 sisaldab Euroopa standardi EN 1639:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 1639:2009 consists of the English text of the European standard EN 1639:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 28.10.2009.	Date of Availability of the European standard text 28.10.2009.
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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.

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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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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)*

EN ISO 7492, *Dental explorers (ISO 7492:1997)*

EN ISO 7711-1, *Dental rotary instruments — Diamond instruments — Part 1: Dimensions, requirements, marking and packaging (ISO 7711-1:1997)*

EN ISO 7711-2, *Dental rotary instruments — Diamond instruments — Part 2: Discs (ISO 7711-2:1992)*

EN ISO 7711-3, *Dentistry— Diamond rotary instruments — Part 3: Grit sizes, designation and colour code (ISO 7711-3:2004)*

EN ISO 7785-1, *Dental handpieces — Part 1: High-speed air turbine handpieces (ISO 7785-1:1997)*

EN ISO 7785-2, *Dental handpieces — Part 2: Straight and geared angle handpieces (ISO 7785-2:1995)*

EN ISO 7885, *Sterile dental injection needles for single use (ISO 7885:2000)*

EN ISO 8325, *Dentistry — Test methods for rotary instruments (ISO 8325:2004)*

EN ISO 9173-1, *Dentistry — Extraction forceps — Part 1: General requirements and test methods (ISO 9173-1:2006)*

EN ISO 9687, *Dental equipment — Graphical symbols (ISO 9687:1993)*

EN ISO 9873, *Dental hand instrument — Reusable mirrors and handles (ISO 9873:1998)*

EN ISO 9997, *Dental cartridge syringes (ISO 9997:1999)*

EN ISO 10323, *Dental rotary instruments — Bore diameters for discs and wheels (ISO 10323:1991)*

EN ISO 11135-1 *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)*

EN ISO 11607-1 *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

EN ISO 11607-2 *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)*

EN ISO 13295, *Dentistry — Mandrels for rotary instruments (ISO 13295:2007)*

EN ISO 13397-1, *Periodontal curettes, dental scalers and excavators — Part 1: General requirements (ISO 13397-1:1995)*

EN ISO 13397-2, *Dentistry — Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes of Gr-type (ISO 13397-2:2005)*

EN ISO 13397-3, *Periodontal curettes, dental scalers and excavators — Part 3: Dental scalers, H-type (ISO 13397-3:1996)*

EN ISO 13397-4, *Periodontal curettes, dental scalers and excavators — Part 4: Dental excavators — Discoid-type (ISO 13397-4:1997)*

EN ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995)*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15087-1, *Dental elevators — Part 1: General requirements (ISO 15087-1:1999)*

EN ISO 15087-2, *Dental elevators — Part 2: Warwick James elevators (ISO 15087-2:2000)*

EN ISO 15087-3, *Dental elevators — Part 3: Cryer elevators (ISO 15087-3:2000)*

EN ISO 15087-4, *Dental elevators — Part 4: Coupland elevators (ISO 15087-4:2000)*

EN ISO 15087-5, *Dental elevators — Part 5: Bein elevators (ISO 15087-5:2000)*

EN ISO 15087-6, *Dental elevators — Part 6: Flohr elevators (ISO 15087-6:2000)*

EN ISO 15098-1, *Dental tweezers — Part 1: General requirements (ISO 15098-1:2000)*

EN ISO 15098-2, *Dental tweezers — Part 2: Meriam types (ISO 15098-2:2000)*

EN ISO 15098-3, *Dental tweezers — Part 3: College types (ISO 15098-3:2000)*

EN ISO 15606, *Dental handpieces — Air-powered scalers and scaler tips (ISO 15606:1999)*

EN ISO 15883-1, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)*

EN ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)*

EN ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

EN ISO 21531, *Dentistry — Graphical symbols for dental instruments (ISO 21531:2009)*

EN ISO 21533, *Dentistry — Reusable cartridge syringes intended for intraligamentary injections (ISO 21533:2003)*

EN ISO 21671, *Dentistry — Rotary polishers (ISO 21671:2006)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 21942-1:1991, EN 21942-3:1993 and the following apply.

3.1
dental instrument
any instrument specially designed for use in the practice of dentistry, which may be hand-operated, power-operated or both

3.2
power-operated dental instrument
dental instrument designed to be activated by an external or internal power source from which it receives the necessary energy for its intended function