EESTI STANDARD EVS-EN 1639:2004

Stomatoloogia. Meditsiinivahendid stomatoloogias. Instrumendid

Dentistry - Medical devices for dentistry - Instruments

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1639:2004 sisaldab Euroopa standardi EN 1639:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 23.09.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 1639:2004 consists of the English text of the European standard EN 1639:2004. This document is endorsed on 23.09.2004 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: 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, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.	**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, sterilization, packaging, marking, labelling, and information supplied by the manufacturer.

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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 17 March 2004.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Contents

Foreword

This document (EN 1639:2004) 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 December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document supersedes EN 1639:1996.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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: Particular 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 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 standard should be used in conjunction with EN 1640, which is applicable for dental equipment. This 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, sterilization, 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 the level 2 and level 3 standards, for dental equipment.

Tests for demonstrating compliance with this European Standard are contained in the level 3 standards, if appropriate.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 550, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization.*

EN 552, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation.*

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*

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, *Graphical symbols for use in the labelling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

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

EN 21942-1, *Dental vocabulary — Part 1: General and clinical terms.*

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

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

EN 26360-2, *Dentistry — Dental rotary instruments — Number coding system — Part 2: Shape and specific characteristics.*

EN 28325, *Dentistry — Dental rotary instruments — Test methods (ISO 8325:1985).*

EN 28601, *Data elements and interchange formats - Information interchange - Representation of dates and times (ISO 8601:1988)*

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

EN 60601-1, *Medical electrical equipment — Part 1: General requirements for safety.*

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 plastic (ISO 1797-2:1992).*

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

EN ISO 3630-1, *Dental root-canal instruments — Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches (ISO 3630-1:1992).*

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 6360-1, *Dentistry - Number coding system for rotary instruments - Part 1: General characteristics (ISO 6360-1:2004)*

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

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, *Dental rotary instruments — Diamond instruments — Part 3: Grit sizes, designation and colour code (ISO 7711-3:1992).*

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 9173-1, *Dental extraction forceps — Part 1: Screw and pin joint types (ISO 9173-1:1991).*

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 13295, *Dental rotary instruments — Mandrels (ISO 13295:1994).*

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

EN ISO 13397-2, *Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes - GR-type (ISO 13397-2:1996).*

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

3 Terms and definitions

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

3.1
dental instrument
any instrument specially designed for use in the practice of dentistry. It may be either 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

3.3
hand-operated dental instrument
dental instrument designed to function in response to the operator's manual movement without any other power source

4 Requirements

4.1 General

4.1.1 Dental instruments shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the instrument concerned. Conformity with these requirements shall be considered to be met by demonstrating compliance with the requirements of the following subclauses, if appropriate.

4.1.2 For instruments intended to be used in connection with items of dental equipment, this standard and EN 1640 shall apply, if appropriate.

4.1.3 Dental instruments used in accordance with the instructions for use shall be safe for their intended purpose in the practice of dentistry.

4.1.4 A risk analysis shall be carried out and documented.

NOTE EN ISO 14971 [2] describes the procedures to be carried out.