EESTI STANDARD EVS-EN 1640:2004

Stomatoloogia. Meditsiinivahendid stomatoloogias. Aparatuur

Dentistry - Medical devices for dentistry - Equipment

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 1640:2004 sisaldab Euroopa standardi EN 1640:2004 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 1640:2004 consists of the English text of the European standard EN 1640:2004. 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 items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer.	**Scope:** This European Standard specifies general requirements for items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer.

ICS 11.060.20

Võtmesõnad:

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1640

June 2004

ICS 11.060.20

Supersedes EN 1640:1996

English version

Dentistry - Medical devices for dentistry - Equipment

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

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Ausrüstung

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.

CEN members are the national standards bodies of 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN 1640:2004: E

Contents

Foreword

This document (EN 1640:2004) 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 1640:1996.

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 those items of dental equipment which are medical devices. For energy sources to be connected to dental instruments, this standard should be used in conjunction with EN 1639, which is applicable for dental instruments. 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 items of dental equipment used in the practice of dentistry and which are medical devices. It includes requirements for intended performance, design attributes, components, packaging, marking, labelling, and information supplied by the manufacturer.

This European Standard does not include requirements for dental X-ray equipment.

This European Standard does not apply to any dental instruments connected to an item of dental equipment. These instruments are covered by the level 2 and level 3 standards for dental instruments.

Tests for demonstrating compliance with this 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 980, *Graphical symbols for use in the labelling of medical devices.*

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

EN 1639, *Dentistry — Medical devices for dentistry — Instruments.*

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

EN 21942-4, *Dental vocabulary — Part 4: Dental equipment (ISO 1942-4:1989).*

EN 60601-1, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988).*

EN 60601-2-22, *Medical electrical equipment — Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995).*

EN 60825-1, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide (IEC 60825-1:1993)*

EN ISO 6875, *Dental equipment - Dental patient chair (ISO 6875:1995)*

EN ISO 7488, *Dental amalgamators (ISO 7488:1991).*

EN ISO 7494, *Dental unit (ISO 7494:1996).*

EN ISO 7494-2, *Dentistry — Dental units — Part 2: Water and air supply (ISO 7494-2:2003).*

EN ISO 9680, *Dental operating light (ISO 9680:1993, including Technical Corrigendum 1:1995).*

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

EN ISO 10637, *Dental equipment — High- and medium-volume suction systems (ISO 10637:1999).*

EN ISO 11143, *Dental equipment — Amalgam separators (ISO 11143:1999).*

EN ISO 11498, *Dental handpieces — Dental low-voltage electrical motors (ISO 11498:1997).*

EN ISO 13294, *Dental handpieces — Dental air-motors (ISO 13294:1997).*