SLOVENSKI STANDARD
SIST EN 1640:2010

01-januar-2010

Nadomeġļa:
SIST EN 1640:2005

Zobozdravstvo - Medicinski pripomoļki za zobozdravstvo - Oprema

Dentistry - Medical devices for dentistry - Equipment

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Ausrüstung

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

Ta slovenski standard je istoveten z: **EN 1640:2009**

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ICS:

11.060.20	Zobotehniļna oprema	Dental equipment

SIST EN 1640:2010 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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SIST EN 1640:2010

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1640

October 2009

ICS 11.060.20

Supersedes EN 1640:2004

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 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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SIST EN 1640:2010
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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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SIST EN 1640:2010

Contents

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63e9-e2d7-4a02-b77a-7def10abd905/sist-en-1640-2010

SIST EN 1640:2010

Foreword

This document (EN 1640:2009) 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 1640:2004.

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 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:

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a) Normative references:

   1) Addition of new relevant product standards, issued after 2004: EN 60601-1-4, EN 62304, EN ISO 7494-1, EN ISO 10650-1, EN ISO 10650-2, EN ISO 14155-1, EN ISO 14155-2, EN ISO 14971, EN ISO 17664, EN ISO 21530;

SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63e9-e2d7-4a02-b77a-7def10ab4905/sist-en-1640-2010

   2) Deletion of the following withdrawn standard: EN ISO 7494.

b) 4.11 Clinical evaluation: Clarification of requirement for a clinical evaluation;

c) 4.12.6 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.

SIST EN 1640:2010

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 items of dental equipment which are medical devices. For energy sources to be connected to dental instruments, this European Standard should be used in conjunction with EN 1639, which is applicable for dental instruments. 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.

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SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63e9-e2d7-4a02-b77a-7def10abd905/sist-en-1640-2010

SIST EN 1640:2010

1 Scope

This European Standard specifies general requirements for 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 apply to 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 EN 1639.

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

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EN 21942-1:1991, *Dental vocabulary — Part 1: General and clinical terms*

EN 21942-4:1993, *Dental vocabulary — Part 4: Dental equipment (ISO 1942-4:1989)*

SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63a9-e2d7-4a02-b77a-7def10abd905/sist-en-1640-2010

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

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

EN 60601-1-4, *Medical electrical equipment — Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems(IEC 60601-1-4:1996)*

EN 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements (IEC 60825-1:2007)*

EN 62304. *Medical device software — Software life-cycle processes (IEC 62304:2006)*

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

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

EN ISO 7494-1, *Dentistry — Dental units — Part 1: General requirements and test methods (ISO 7494-1:2004)*

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

EN ISO 9680, *Dentistry — Operating lights (ISO 9680:2007)*

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 10650-1, *Dentistry — Powered polymerization activators — Part 1: Quartz tungsten halogen lamps (ISO 10650-1:2004)*

SIST EN 1640:2010

EN ISO 10650-2, *Dentistry — Powered polymerization activators — Part 2: Light-emitting diode (LED) lamps (ISO 10650-2:2007)*

EN ISO 11143, *Dentistry — Amalgam separators (ISO 11143:2008)*

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

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

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

EN ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants (ISO 21530:2004)*

3 Terms and definitions

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For the purposes of this European Standard, the terms and definitions given in EN 21942-1:1991, EN 21942-4:1993 and the following apply.

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3.1
dental equipment

SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63e9-e2d7-4a02-b77a-

furniture, machines, apparatus and accessories thereto, specially made and/or presented for the use of authorized persons in the practice of dentistry and/or its associated procedures

4 Requirements

4.1 General

4.1.1 Dental equipment shall comply with the requirements which are applicable to them bearing in mind the intended purpose of the equipment 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 those items of dental equipment intended to be used in connection with dental instruments, this standard and EN 1639 shall apply, if appropriate.

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

4.1.4 Risk management shall be carried out and documented. This shall include a risk analysis in accordance with EN ISO 14971.

4.2 Chemical and physical properties

4.2.1 Materials

Dental equipment shall comply with the material requirements as specified in the following product standards, if appropriate:

EN ISO 6875, EN ISO 7494-1, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, EN ISO 11143; EN ISO 21530.

SIST EN 1640:2010

NOTE Amalgam separators are considered to be medical devices only when incorporated as an integral part of the dental unit.

4.2.2 Contaminants and residues

Dental equipment shall be designed and manufactured so that the transfer of contaminants and residues does not compromise the clinical condition or the safety of patients, or the safety and health of users. Design specifications are given in the product standards. The following standards shall apply, if appropriate:

EN ISO 6875, EN ISO 7494-1, EN ISO 7494-2, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294, EN ISO 21530.

NOTE For plant area equipment further information is given in ISO/TS 22595-1 and 22595-2.

4.2.3 Contact with substances

Dental equipment shall satisfy the performance requirements for safe use with water, gases, oil, and other substances with which they enter into contact during normal use. The following standards shall apply, if appropriate:

EN ISO 6875, EN ISO 7494-1, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.2.4 Ingress and leaking of substances

Dental equipment shall be safe in regard to any risks due to ingress or leakage or both of water, gases, oil, and other substances during normal use. The following standards shall apply, if appropriate:

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(standards.iteh.ai)

EN 60601-1, EN ISO 6875, EN ISO 7488, EN ISO 7494-1, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 21530.

SIST EN 1640:2010
https://standards.iteh.ai/catalog/standards/sist/738b63e9-e2d7-4a02-b77a-7def10abd905/sist-en-1640-2010

4.3 Control of contamination

Dental equipment shall be designed and manufactured so as to facilitate infection control. The following standards shall apply, if applicable:

EN ISO 7494-1, EN ISO 7494-2, EN ISO 17664, EN ISO 21530.

4.4 Construction and environmental properties

4.4.1 Dental equipment shall be designed and manufactured so that its physical and dimensional characteristics are suitable for its intended use and its use in combination according to the instructions for use. Connections to other devices shall be safe and create no risk due to physical features such as pressure or temperature or by accidental disconnection. The following standards shall apply, if appropriate:

EN 60601-1, EN 60601-2-22, EN 60825-1, EN ISO 6875, EN ISO 7494-1, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, EN ISO 10650-1, EN ISO 10650-2, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.4.2 Dental equipment shall be designed and manufactured so that fire or explosion due to the use of any other substance shall be avoided. The following standards shall apply, if appropriate:

EN ISO 6875, EN ISO 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 11143.

4.5 Protection against radiation

4.5.1 Dental equipment emitting radiation shall be accompanied by detailed instructions which inform about the safe installation, use and possible risks of the equipment. The following standards shall apply, if appropriate:

EN 60601-1, EN 60601-2-22, EN 60825-1, EN ISO 9680, EN ISO 10650-1, EN ISO 10650-2.

4.5.2 Dental equipment shall be designed and manufactured so that unintended radiation is reduced as far as possible.