SLOVENSKI STANDARD
SIST EN 1640:2005

01-januar-2005

Nadomeġļa:
SIST EN 1640:2000

Zobozdravstvo - Medicinski pripomoļki za zobozdravstvo - Oprema

Dentistry - Medical devices for dentistry - Equipment

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Ausrüstung

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

Ta slovenski standard je istoveten z: EN 1640:2004

ICS:

11.060.20	Zobotehniļna oprema	Dental equipment

SIST EN 1640:2005 **en,fr,de**

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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.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).*

3 Terms and definitions

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

3.1
dental equipment
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 A risk analysis shall be carried out and documented.

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

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, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, EN ISO 11143.

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 to the patient and the dental personnel is minimized. Design specifications are given in the product standards. The following standards shall apply, if appropriate:

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

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, 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:

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

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, EN ISO 7494-2.

4.4 Construction and environmental properties

4.4.1 Dental equipment shall be designed and manufactured so that their physical and dimensional characteristics are suitable for their intended use and their 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, EN ISO 7494-2, EN ISO 9680, EN ISO 10637, 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, EN ISO 9860, 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.

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

4.6 Equipment connected to or equipped with an energy source

Dental equipment, internally or externally equipped with or connected to a power source and/or controlled by electronic programmable systems or both, shall be designed and manufactured to minimize the risk of personal injury during normal use. If the safety of the patient depends on the correct functioning of the equipment, an adequate alarm system or means of determining the state of the energy supply or both shall be installed. The following standards shall apply, if appropriate:

EN 60601-1, EN 60601-2-22, EN 60825-1, EN ISO 6875, EN ISO 7488, EN ISO 7494, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.7 Protection against electrical risks

Dental equipment, internally or externally equipped with or connected to an electrical power source or both, shall be safe so as to avoid as far as possible the risk of electrical shock during normal use and under single fault conditions. The following standards shall apply, if appropriate:

EN 60601-1, EN 60601-2-22, EN 60825-1, EN ISO 6875, EN ISO 7488, EN ISO 7494, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294.