SLOVENSKI STANDARD
SIST EN 1640:2000

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Zobozdravstvo - Medicinski pripomoļ ki za zobozdravstvo - Oprema

Dentistry - Medical devices for dentistry - Equipment

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Ausrüstung

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

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ICS:

11.060.20 Zobotehniļ na oprema Dental equipment

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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 1996-07-04. 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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

This European standard has been prepared by Technical Committee CEN/TC 55 'Dentistry', the secretariat of which is held by DIN.

This European Standard 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 standard.

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of an identical text or by endorsement, at the latest by February 1997, and conflicting national standards shall be withdrawn at the latest by February 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

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 informative annex A a reference for guidance on the classification of medical devices used in dentistry [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 standard does not include requirements for dental X-ray equipment.

This 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 references 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.

EN 980	Graphical symbols for use in the labelling of medical devices
prEN 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
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times
EN 60601-1	Medical electrical equipment - Part 1: General requirements for safety

EN 60825	Radiation safety of laser products, equipment, classification, requirements and user's guide
prEN ISO 6875	Dental patient chair
EN ISO 7488	Dental amalgamators
ISO 7494	Dental unit
EN ISO 9680	Dental operating light
EN ISO 9687	Dental equipment - Graphical symbols
ISO/DIS 11498	Dental handpieces - Dental low voltage motors
prEN ISO 13294	Dental air motors

3 Definitions

For the purposes of this standard the definitions of EN 21942-1 and EN 21942-4 apply:

dental equipment

Furniture, machines, apparatus and accessories thereto, specially manufactured and/or presented for the use of authorized persons in the practice of dentistry and/or its associated procedures. [EN 21942-1:1991]

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 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 it's intended purpose in the practice of dentistry.

4.1.4 For dental equipment a risk analysis shall be carried out and documented.

NOTE: EN 1441 describes a procedure for carrying out and documenting a risk analysis of medical devices.

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:

prEN ISO 6875, ISO 7494, EN ISO 9680.

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:

prEN 6875, ISO 7494, ISO/DIS 11498, prEN 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:

prEN ISO 6875, ISO 7494, EN ISO 9680, ISO/DIS 11498, prEN 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, prEN ISO 6875, EN ISO 7488, ISO 7494, EN ISO 9680.

4.3 Control of contamination

Dental equipment shall be designed and manufactured so as to facilitate infection control.

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 accidential disconnection. The following standards shall apply, if appropriate:

EN 60601-1, prEN ISO 6875, ISO 7494, EN ISO 9680, ISO/DIS 11498, prEN 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:

prEN ISO 6875, ISO 7494, EN ISO 9680.

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 60825, 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 ISO 9680, prEN ISO 6875, ISO 7494, ISO/DIS 11498, prEN 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 60825, prEN ISO 6875, ISO 7494, EN ISO 9680, ISO/DIS 11498, prEN ISO 13294.

4.8 Protection against mechanical and thermal risks

4.8.1 Mechanical stability

Dental equipment shall be designed and manufactured to remain stable under normal conditions of use. The safe load and distribution of any accessory shall be specified. No moving part shall constitute a risk to the patient or dental personnel. The following standards shall apply, if appropriate:

prEN ISO 6875, ISO 7494, EN ISO 9680.

4.8.2 Vibration

Dental equipment shall be designed and manufactured to minimize the risk of personal injury from vibration. The following standards shall apply, if appropriate:

ISO/DIS 11498, prEN ISO 13294.

4.8.3 Noise

Dental equipment shall be designed and manufactured to minimize the risk of personal injury from noise. The following standards shall apply, if appropriate:

ISO/DIS 11498, prEN ISO 13294.

4.8.4 Electricity, gas, hydraulic and pneumatic energy

Dental equipment shall be designed and manufactured so that their connections to electrical or other sources of energy shall avoid as far as possible the risk of personal injury. The following standards shall apply, if appropriate:

prEN ISO 6875, ISO 7494, EN ISO 9680, ISO/DIS 11498, prEN ISO 13294.

4.8.5 Surface temperature

Dental equipment shall be designed and manufactured so as to avoid hazardous overheating. The following standards shall apply, if appropriate:

prEN ISO 6875, ISO 7494, ISO/DIS 11498, prEN ISO 13294.

4.9 Controls and indicators

Controls and indicators for dental equipment shall be identifiable. Controls shall be located in a position or be of such design that they cannot be accidentally activated. The following standards shall apply, if appropriate:

prEN ISO 6875, ISO 7494, EN ISO 9680, EN ISO 9687, ISO/DIS 11498, prEN ISO 13294.

4.10 Marking, labelling and information supplied by the manufacturer

4.10.1 General

4.10.1.1 Information required for the safe use of dental equipment shall be provided by the manufacturer in accordance with EN 980, prEN 1041, EN 60601-1, relevant product standards, and 4.10.2, 4.10.3, 4.10.4, 4.10.5 and 4.10.6.