SLOVENSKI STANDARD
SIST EN 1639:2000

01-januar-2000

Zobozdravstvo - Medicinski pripomočki za zobozdravstvo - Instrumenti

Dentistry - Medical devices for dentistry - Instruments

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Instrumente

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

Ta slovenski standard je istoveten z: **EN 1639:1996**

ICS:

11.060.25 Zobotehnični instrumenti Dental instruments

SIST EN 1639:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1639

August 1996

ICS 11.060.20

Descriptors: dentistry, dental instruments, specifications, information, labelling, technical notes

English version

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 1996-07-12. 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 the 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 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 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 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 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 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 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	Sterilization of medical devices - Requirements for medical devices to be labelled 'STERILE'
EN 980	Graphical symbols for use in the labelling of medical devices
prEN 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
EN 22157	Dental rotary instruments - Nominal sizes and designation
EN 23630-2	Dental root canal instruments - Part 2: Enlargers
EN 23823-1	Dental rotary instruments - Part 1: Steel and carbide burs
EN 23823-2	Dental rotary instruments - Part 2: Steel and carbide finishing burs

EN 23964	Dentistry - Dental handpieces - Coupling dimensions
EN 26360-1	Dental rotary instruments - Number coding system - Part 1: General characteristics
EN 26360-2	Dental rotary instruments - Number coding system - Part 2: Shape and specific characteristics
EN 27711	Dentistry - Dental rotary instruments - Diamond instruments
EN 27785-1	Dental handpieces - Part 1: High speed air turbine handpieces
EN 27785-2	Dental handpieces - Part 2: Straight and geared angled handpieces
EN 28325	Dentistry - Dental rotary instruments - Test methods
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times
EN 29168	Dental handpieces - Hose connectors
EN 29873	Reusable metal dental mirrors and handles
EN 29997	Dental cartridge syringes
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
EN ISO 1797-2	Dental rotary instruments - Shanks - Part 2: Shanks made of plastics
EN ISO 3630-1	Dental root-canal instruments - Part 1: Files, reamers, barbed broaches, rasps, paste, carriers, explorers and cotton broaches
EN ISO 3630-3	Dental root canal instruments - Part 3: Condensers, pluggers and spreaders
EN ISO 7711-2	Dental rotary instruments - Diamond instruments - Part 2: Discs
EN ISO 7711-3	Dental rotary instruments - Diamond instruments - Part 3: Grit sizes, designation and colour code
EN ISO 9173-1	Dental extraction forceps - Part 1: Screw and pin joint types
EN ISO 9687	Dental equipment - Graphical symbols
EN ISO 10323	Dental rotary instruments - Bore diameters for discs and wheels
EN ISO 13397-1	Periodontal curettes, dental scalers and excavators- Part 1: General requirements
EN ISO 13397-2	Periodontal curettes, dental scalers and excavators - Part 2: Periodontal curettes - Gr-typ
EN ISO 13397-3	Periodontal curettes, dental scalers and excavators - Part 3: Dental scalers - H-type

3 Definitions

For the purposes of this standard the definitions of EN 21942-1, EN 21942-3 and the following definitions 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 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 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 For dental instruments 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 General

4.2.1.1 Material properties

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

EN 23630-2, EN 23823-1, EN 23823-2, EN 27711, EN 27785-1, EN 27785-2, EN 29873, EN 29997, EN ISO 1797-1, EN ISO 1797-2, EN ISO 3630-1, EN ISO 3630-3, EN ISO 7711-2, EN ISO 9173-1, EN ISO 13397-1.

4.2.1.2 Physical properties

Dental instruments shall comply with the physical properties (for example strength, bending and torque) as specified in the following standards, if appropriate:

EN 23630-2, EN 23823-1, EN 23823-2, EN 27711, EN 27785-1, EN 27785-2, EN 29873, EN 29997, EN ISO 1797-1, EN ISO 1797-2, EN ISO 3630-1, EN ISO 3630-3, EN ISO 7711-2, EN ISO 7711-3, EN ISO 9173-1, EN ISO 13397-1.

Appropriate test methods for dental rotary instruments for diameter, length, run-out and other properties are specified in EN 28325.

4.2.2 Contaminants and residues

Dental instruments 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 27785-1, EN 27785-2, EN 29168, EN 29873, EN 29997, EN ISO 3630-1, EN ISO 3630-3, EN ISO 9173-1, EN ISO 13397-1, EN ISO 13397-2, EN ISO 13397-3.

4.2.3 Contact with substances

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

EN 27785-1, EN 27785-2, EN 29168.

4.3 Control of contamination

4.3.1 General

4.3.1.1 If dental instruments are provided both in sterile and non-sterile conditions the condition in which they are supplied shall be clearly indicated.

4.3.1.2 Reusable dental instruments shall be capable of being resterilized.

4.3.2 Instruments supplied sterile

4.3.2.1 Dental instruments supplied sterile shall comply with EN 556.

4.3.2.2 Sterilization processes shall be validated and routinely controlled:

a) If dental instruments are to be sterilized by ethylene oxide, EN 550 shall apply;
b) If dental instruments are to be sterilized by irradiation, EN 552 shall apply;
c) If dental instruments are to be sterilized by moist heat, EN 554 shall apply.

4.3.2.3 Packaging systems for dental instruments supplied sterile shall be such that the instruments remain sterile until the package is opened.

4.3.2.4 The product standards shall be complied with, if appropriate.

4.3.3 Instruments supplied non-sterile

4.3.3.1 Product-related risks of contamination to the patient and the dental personnel shall be reduced by specific sterilization methods given in the following standards, if appropriate:

EN 27785-1, EN 27785-2, EN 29873, EN 29997, EN ISO 3630-1, EN ISO 9173-1, EN ISO 13397-1.

4.3.3.2 Packaging systems for dental instruments supplied non-sterile shall maintain the level of cleanliness of the instruments during transport and storage.

4.3.3.3 The product standards shall be complied with, if appropriate.