BRITISH STANDARD

BS EN 1639:2009

Dentistry — Medical devices for dentistry — Instruments

ICS 11.060.25

National foreword

This British Standard is the UK implementation of EN 1639:2009. It supersedes BS EN 1639:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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Zahnheilkunde - Medizinprodukte für die Zahnheilkunde - Instrumente

This European Standard was approved by CEN on 19 September 2009.

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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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Contents

Foreword

This document (EN 1639:2009) 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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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 1639:2004.

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(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following changes were made:

a) Normative references:

   1) Addition of new relevant product standards, issued after 2004: EN 13060, EN ISO 8325, EN ISO 11135-1, EN ISO 11137-1, EN ISO 11607-1, EN ISO 11607-2, EN ISO 14155-1, EN ISO 14155-2, EN ISO 14971, EN ISO 15883-1, EN ISO 17664, EN ISO 17665-1 and EN ISO 21571;

   2) Deletion of the following withdrawn standards: EN 550, EN 552, EN 554, EN 26360-2 and EN 28325.

b) 4.7 Clinical evaluation: Clarification of requirement for a clinical evaluation;

c) 4.10.6 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.

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 instruments used in the practice of dentistry. For instruments to be connected to an energy source, this European Standard should be used in conjunction with EN 1640, which is applicable for dental equipment. 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.

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, reprocessing, packaging, marking, labelling, and information supplied by the manufacturer.

This European Standard does not apply to any necessary energy source to which an instrument needs to be connected. These energy sources are covered by EN 1640.

Tests for demonstrating compliance with this European 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 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 1640, *Dentistry — Medical devices for dentistry — Equipment*

EN 13060, *Small steam sterilizers*

EN 21942-1:1991, *Dental vocabulary — Part 1: General and clinical terms (ISO 1942-1:1989)*

EN 21942-3:1993, *Dental vocabulary — Part 3: Dental instruments (ISO 1942-3:1989)*

EN 23964, *Dentistry — Dental handpieces — Coupling dimensions (ISO 3964:1982)*

EN 29168, *Dental handpieces — Hose connectors (ISO 9168:1991)*

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

EN ISO 1797-1, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals (ISO 1797-1:1992)*

EN ISO 1797-2, *Dental rotary equipment — Shanks — Part 2: Shanks made of plastics (ISO 1797-2:1992)*

EN ISO 2157, *Dental rotary instruments — Nominal diameters and designation code number (ISO 2157:1992)*

EN ISO 3630-1, *Dentistry — Root-canal instruments — Part 1: General requirements and test methods (ISO 3630-1:2008)*

EN ISO 3630-2, *Dental root-canal instruments — Part 2: Enlargers (ISO 3630-2:2000)*

EN ISO 3630-3, *Dental root-canal instruments — Part 3: Condensers, pluggers and spreaders (ISO 3630-3:1994)*

EN ISO 3823-1, *Dental rotary instruments — Burs — Part 1: Steel and carbide burs (ISO 3823-1:1997)*

EN ISO 3823-2, *Dentistry — Rotary bur instruments — Part 2: Finishing burs (ISO 3823-2:2003)*

EN ISO 7153-1, *Surgical instruments — Metallic materials — Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999)*

EN ISO 7492, *Dental explorers (ISO 7492:1997)*

EN ISO 7711-1, *Dental rotary instruments — Diamond instruments — Part 1: Dimensions, requirements, marking and packaging (ISO 7711-1:1997)*

EN ISO 7711-2, *Dental rotary instruments — Diamond instruments — Part 2: Discs (ISO 7711-2:1992)*

EN ISO 7711-3, *Dentistry— Diamond rotary instruments — Part 3: Grit sizes, designation and colour code (ISO 7711-3:2004)*

EN ISO 7785-1, *Dental handpieces — Part 1: High-speed air turbine handpieces (ISO 7785-1:1997)*

EN ISO 7785-2, *Dental handpieces — Part 2: Straight and geared angle handpieces (ISO 7785-2:1995)*

EN ISO 7885, *Sterile dental injection needles for single use (ISO 7885:2000)*

EN ISO 8325, *Dentistry — Test methods for rotary instruments (ISO 8325:2004)*

EN ISO 9173-1, *Dentistry — Extraction forceps — Part 1: General requirements and test methods (ISO 9173-1:2006)*

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

EN ISO 9873, *Dental hand instrument — Reusable mirrors and handles (ISO 9873:1998)*

EN ISO 9997, *Dental cartridge syringes (ISO 9997:1999)*

EN ISO 10323, *Dental rotary instruments — Bore diameters for discs and wheels (ISO 10323:1991)*

EN ISO 11135-1 *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)*

EN ISO 11607-1 *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

EN ISO 11607-2 *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)*

EN ISO 13295, *Dentistry — Mandrels for rotary instruments (ISO 13295:2007)*

EN ISO 13397-1, *Periodontal curettes, dental scalers and excavators — Part 1: General requirements (ISO 13397-1:1995)*

EN ISO 13397-2, *Dentistry — Periodontal curettes, dental scalers and excavators — Part 2: Periodontal curettes of Gr-type (ISO 13397-2:2005)*

EN ISO 13397-3, *Periodontal curettes, dental scalers and excavators — Part 3: Dental scalers, H-type (ISO 13397-3:1996)*

EN ISO 13397-4, *Periodontal curettes, dental scalers and excavators — Part 4: Dental excavators — Discoid-type (ISO 13397-4:1997)*

EN ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995)*

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 15087-1, *Dental elevators — Part 1: General requirements (ISO 15087-1:1999)*

EN ISO 15087-2, *Dental elevators — Part 2: Warwick James elevators (ISO 15087-2:2000)*

EN ISO 15087-3, *Dental elevators — Part 3: Cryer elevators (ISO 15087-3:2000)*

EN ISO 15087-4, *Dental elevators — Part 4: Coupland elevators (ISO 15087-4:2000)*

EN ISO 15087-5, *Dental elevators — Part 5: Bein elevators (ISO 15087-5:2000)*

EN ISO 15087-6, *Dental elevators — Part 6: Flohr elevators (ISO 15087-6:2000)*

EN ISO 15098-1, *Dental tweezers — Part 1: General requirements (ISO 15098-1:2000)*

EN ISO 15098-2, *Dental tweezers — Part 2: Meriam types (ISO 15098-2:2000)*

EN ISO 15098-3, *Dental tweezers — Part 3: College types (ISO 15098-3:2000)*

EN ISO 15606, *Dental handpieces — Air-powered scalers and scaler tips (ISO 15606:1999)*

EN ISO 15883-1, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)*

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 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

EN ISO 21531, *Dentistry — Graphical symbols for dental instruments (ISO 21531:2009)*

EN ISO 21533, *Dentistry — Reusable cartridge syringes intended for intraligamentary injections (ISO 21533:2003)*

EN ISO 21671, *Dentistry — Rotary polishers (ISO 21671:2006)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 21942-1:1991, EN 21942-3:1993 and the following apply.

3.1
dental instrument
any instrument specially designed for use in the practice of dentistry, which may be 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 manual 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 requirements of 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.

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 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 General

4.2.1.1 Material properties

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

EN ISO 1797-1, EN ISO 1797-2, EN ISO 3630-1, EN ISO 3630-2, EN ISO 3630-3, EN ISO 3823-1, EN ISO 3823-2, EN ISO 7153-1, EN ISO 7492, EN ISO 7711-1, EN ISO 7711-2, EN ISO 7711-3, EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 13295, EN ISO 13397-1, EN ISO 13402, EN ISO 15087-1, EN ISO 15098-1, EN ISO 15606, EN ISO 21671.

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 23964, EN 29168, EN ISO 1797-1, EN ISO 1797-2, EN ISO 3630-1, EN ISO 3630-2, EN ISO 3630-3, EN ISO 3823-1, EN ISO 3823-2, EN ISO 7492, EN ISO 7711-1, EN ISO 7711-2, EN ISO 7711-3, EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 10323, EN ISO 13295, EN ISO 13397-1, EN ISO 13397-2, EN ISO 13397-3, EN ISO 13397-4, EN ISO 15087-1, EN ISO 15087-2, EN ISO 15087-3, EN ISO 15087-4, EN ISO 15087-5, EN ISO 15087-6, EN ISO 15098-1, EN ISO 15098-2, EN ISO 15098-3, EN ISO 15606, EN ISO 21533, EN ISO 21671.

Test methods for dental rotary instruments for diameter, length, run-out and other requirements are specified in EN ISO 8325.

4.2.2 Contaminants and residues

Dental instruments 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 29168, EN ISO 3630-1, EN ISO 3630-2, EN ISO 3630-3, EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 13397-1, EN ISO 13397-2, EN ISO 13397-3,

EN ISO 13397-4, EN ISO 15087-1, EN ISO 15087-2, EN ISO 15087-3, EN ISO 15087-4, EN ISO 15087-5, EN ISO 15087-6, EN ISO 15098-1, EN ISO 15098-2, EN ISO 15098-3, EN ISO 15606, EN ISO 21533, EN ISO 21671.

4.2.3 Contact with substances

Dental instruments shall satisfy the performance requirements for safe use with substances with which they come into contact during normal use. The following standards shall apply, if appropriate:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 15606, EN 29168.

4.3 Control of contamination

4.3.1 General

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

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

4.3.1.3 Reusable dental instruments shall be capable of being reprocessed. For reprocessing of dental instruments EN ISO 17664 shall apply.

4.3.2 Instruments supplied sterile

4.3.2.1 Dental instruments supplied sterile shall comply with EN 556-1.

4.3.2.2 Sterilization processes shall be validated and regularly checked:

a) If dental instruments are to be sterilized by ethylene oxide, EN ISO 11135-1 shall apply;

b) If dental instruments are to be sterilized by irradiation, EN ISO 11137-1 shall apply;

c) If dental instruments are to be sterilized by moist heat, EN ISO 17665-1 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 before the expiry date. The product standards for the packaging systems shall be complied with, if appropriate.

Packaging systems for dental instruments supplied sterile shall be in accordance with EN ISO 11607-1 and EN ISO 11607-2.

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 reprocessing methods given in the following standards, if appropriate:

EN 13060, EN ISO 3630-1, EN ISO 7785-1, EN ISO 7785-2, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 13397-1, EN ISO 13402, EN ISO 15883-1, EN ISO 15087-1, EN ISO 15098-1, EN ISO 15606.

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. The product standards for the packaging systems shall be complied with, if appropriate.

4.4 Construction and environmental properties

4.4.1 Dental instruments 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 dental devices shall be safe and create no risk due to physical features such as pressure or temperature or by accidental disconnection.

4.4.2 Moving parts shall be designed and manufactured so that accidental personal injury is minimized.

4.4.3 Design specifications are given in the product standards. The following standards shall apply, if appropriate:

EN 23964, EN 29168, EN ISO 1797-1, EN ISO 1797-2, EN ISO 2157, EN ISO 3630-1, EN ISO 3630-2, EN ISO 3630-3, EN ISO 3823-1, EN ISO 3823-2, EN ISO 7492, EN ISO 7711-1, EN ISO 7711-2, EN ISO 7711-3, EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 10323, EN ISO 13295, EN ISO 13397-2, EN ISO 13397-3, EN ISO 13397-4, EN ISO 15087-1, EN ISO 15087-2, EN ISO 15087-3, EN ISO 15087-4, EN ISO 15087-5, EN ISO 15087-6, EN ISO 15098-1, EN ISO 15098-2, EN ISO 15098-3, EN ISO 15606, EN ISO 21533, EN ISO 21671.

4.5 Instruments connected to or equipped with an energy source

For power-operated dental instruments the energy source shall comply with the following standards, if appropriate, to minimize the risk of personal injury:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 15606, EN 29168, EN 60601-1.

4.6 Protection against electrical risks

Power-operated dental instruments, internally or externally equipped with or connected to an electrical power source, shall be designed and manufactured 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 ISO 7785-1, EN ISO 7785-2, EN 29168, EN 60601-1.

4.7 Protection against mechanical and thermal risks

4.7.1 Vibration

Power-operated dental instruments shall be designed and manufactured to minimize the risk of personal injury from vibration. The following standards shall apply, if appropriate:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 15606.

4.7.2 Noise

Power-operated dental instruments shall be designed and manufactured to minimize the risk of personal injury from noise. The following standards shall apply, if appropriate:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 15606.

4.7.3 Electricity, gas or hydraulic and pneumatic energy

Power-operated dental instruments 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:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 15606, EN 60601-1.

4.7.4 Surface temperature

Power-operated dental instruments shall be designed and manufactured so as to avoid hazardous overheating. The following standards shall apply, if appropriate:

EN ISO 7785-1, EN ISO 7785-2, EN ISO 15606.

4.8 Controls and indicators

Controls and indicators for dental instruments shall be identifiable.

NOTE Identification by colour is an appropriate method.

The following standards shall apply, if appropriate:

EN ISO 3630-1, EN ISO 7711-3, EN ISO 7785-1, EN ISO 7785-2.

4.9 Clinical evaluation

A clinical evaluation shall be conducted and reported for all dental instruments.

Clinical investigation of dental instruments, if appropriate, shall be conducted in accordance with EN ISO 14155-1 and EN ISO 14155-2.

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 instruments shall be provided by the manufacturer in accordance with EN 980, EN 1041, EN 60601-1, 4.10.2, 4.10.3, 4.10.4, 4.10.5 and 4.10.6, and the following standards, if appropriate:

EN 23964, EN 29168, EN ISO 1797-1, EN ISO 1797-2, EN ISO 2157, EN ISO 3630-1, EN ISO 3630-2, EN ISO 3630-3, EN ISO 3823-1, EN ISO 3823-2, EN ISO 7492, EN ISO 7711-1, EN ISO 7711-2, EN ISO 7711-3, EN ISO 7785-1, EN ISO 7785-2, EN ISO 7885, EN ISO 9173-1, EN ISO 9873, EN ISO 9997, EN ISO 10323, EN ISO 13295, EN ISO 13397-2, EN ISO 13397-3, EN ISO 13397-4, EN ISO 15087-1, EN ISO 15087-2, EN ISO 15087-3, EN ISO 15087-4, EN ISO 15087-5, EN ISO 15087-6, EN ISO 15098-1, EN ISO 15098-2, EN ISO 15098-3, EN ISO 15606, EN ISO 21533, EN ISO 21671.

4.10.1.2 The information shall be provided, at least, as marking on the instrument, or on a label of the primary container, or on the packaging or in instructions for use, if appropriate.

4.10.1.3 If it is not practicable for all the required information as stated in 4.10.2, 4.10.3 and 4.10.4 to be included on the label of the primary container then the relevant information shall be provided on the next layer of packaging or included within the instructions for use.

4.10.2 Symbols

Marking, labelling and instructions for use of dental instruments shall, if appropriate, include information in the form of symbols as specified in the following standards:

EN 980, EN ISO 9687, EN ISO 21531.

4.10.3 Marking

Dental instruments shall be marked, if applicable, in accordance with the relevant standard. Marking shall include the following minimum information:

a) Name or registered trade mark of manufacturer;

b) Trade name, or catalogue number;

c) Other relevant identification characteristics;

d) Batch code, preceded by the word "LOT" or the symbol LOT; or the serial number preceded by SN.

4.10.4 Label

4.10.4.1 The label shall include the following minimum information:

a) name or trade name and address of the manufacturer. For dental instruments imported into the Community the name and address of the authorized representative, if the manufacturer does not have a registered place of business in the Community;

b) description of the contents, including name, description and quantities;

c) the word "STERILE" or the symbol STERILE, the method of sterilization and the recommended method of opening the pack to ensure sterile presentation at time of use, if appropriate;

d) batch code, preceded by the word "LOT" or the symbol LOT;

e) "Use by" date expressed in accordance with ISO 8601, if appropriate;

f) the words "exclusively for clinical investigation", if the dental instrument is intended for clinical investigations;

g) indication that it is for single use, if appropriate;

h) special cleaning and sterilization instructions, if appropriate;

i) special storage and/or handling conditions, or operating instructions;

j) warnings and/or precautions to take.

4.10.4.2 Where transparent packages are used and the marking on the instrument is clearly visible it is unnecessary to duplicate the information on the label of the packaging or in the instructions for use.

4.10.5 Detachable components

Detachable components from the instruments shall be identified, if appropriate, to enable it to be traced to the original item.

4.10.6 Instructions for use

4.10.6.1 Instructions for the safe operation of dental instruments shall be provided except in the case of those instruments in class I and class IIa which can be used safely by dental personnel without instructions for use.

NOTE The classification of medical devices used in dentistry is defined by Council Directive 93/42 EEC [1]. Additional information is given in [3].

4.10.6.2 The instructions for use shall include at least the following information:

a) details referred to in 4.10.3 and 4.10.4 with the exception of 4.10.3 d) and 4.10.4.1 d) and e);

b) intended purpose of the dental instrument and any restrictions on use;

c) sufficient details of its characteristics to identify the correct materials, equipment and procedures to be used in order to obtain a safe combination, if the dental instrument is intended to be connected to or used in combination with other devices;

d) action to be taken in the event of damage to the packaging of dental instrument supplied sterile, if appropriate;

e) details of any further treatment or handling needed before the dental instrument can be used (for example, final assembly);

f) characteristics and technical factors known to the manufacturer that could pose a risk if the dental instrument were to be re-used;

g) instructions for reprocessing, if the dental instrument is intended for re-use;

h) date of issue of the instructions for use;

i) should additional information be provided by the manufacturer in electronic format, then the means of accessing this information shall be given.

NOTE Additional Information for the user may be provided at the discretion of the manufacturer in an electronic format (e.g. webpage, DVD).

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC concerning medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this EN	Essential Requirements (Ers) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1 to 6	
4.2.1	7.1	
4.2.2	7.2	
4.2.3	7.3	
4.3.1	8.7	
4.3.2	8.3	
4.3.3	8.6	
4.4	9.1, 9.2	
4.5	12	
4.6	12.6	
4.7.1	12.7.2	
4.7.2	12.7.3	
4.7.3	12.7.4	
4.7.4	12.7.5	
4.8	12.9	
4.9	6 a)	
4.10.1	13.1	
4.10.2	13.2	
4.10.3	13.3	
4.10.4	13.3	
4.10.5	13.5	
4.10.6	13.6	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

[1] 93/42/EEC Council Directive of 14 June 1993, amended by Directive 2007/47/EC, concerning medical devices, Official Journal of the European Union (OJEU), L. 169 from 12.07.1993, page 1-43

[2] MEDDEV 2.7.1, European Commission, Guidelines on Medical Devices (MedDev), Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies, Version 2.7.1, April 2003

[3] CEN/TR 12401, *Dentistry — Guidance on the classification of dental devices and accessories*

[4] EN ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity (ISO 3950:1995)*

[5] EN ISO 11499, *Dentistry — Single-use cartridges for local anaesthetics (ISO 11499:2007)*

BSI - British Standards Institution

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