BRITISH STANDARD

BS EN 1640:2009

Dentistry — Medical devices for dentistry — Equipment

ICS 11.060.20

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN 1640:2009. It supersedes BS EN 1640:2004 which is withdrawn.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.

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Contents

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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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:

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;

   2) Deletion of the following withdrawn standard: EN ISO 7494.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

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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.

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*

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)*

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)*

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

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.

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 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.

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:

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.

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.

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 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 10650-1, EN ISO 10650-2, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.7 Programmable electronic subsystems (software programmes)

If dental equipment incorporates software the following standards shall apply, if appropriate:

EN 60601-1-4, EN 62304.

For stand alone software which is also a medical device the following standards shall apply, if appropriate:

EN 60601-4, EN 62304.

4.8 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 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 10650-1, EN ISO 10650-2, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.9 Protection against mechanical and thermal risks

4.9.1 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 hazard to the patient or dental personnel. The following standards shall apply, if appropriate:

EN ISO 6875, EN ISO 7488, EN ISO 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 10650-1, EN ISO 10650-2.

4.9.2 Vibration

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

EN ISO 11498, EN ISO 13294.

4.9.3 Noise

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

EN ISO 10637, EN ISO 11498, EN ISO 13294.

4.9.4 Electricity, gas, hydraulic and pneumatic energy

Dental equipment shall be designed and manufactured so that its 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 6875, EN ISO 7488, EN ISO 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.9.5 Surface temperature

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

EN ISO 6875, EN ISO 7494-1, EN ISO 9680, EN ISO 11498, EN ISO 13294.

4.10 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:

EN ISO 6875, EN ISO 7488, EN ISO 7494-1, EN ISO 9680, EN ISO 10637, EN ISO 11143, EN ISO 11498, EN ISO 13294.

4.11 Clinical evaluation

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

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

4.12 Marking, labelling and information supplied by the manufacturer

4.12.1 General

4.12.1.1 Information required for the safe use of dental equipment shall be provided by the manufacturer in accordance with EN 980, EN 1041, EN 60601-1, EN 60601-2-22, EN 60825-1, relevant product standards and 4.12.2, 4.12.3, 4.12.4, 4.12.5 and 4.12.6, and the following standards, if appropriate:

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.

4.12.1.2 The information required for the safe use of the equipment shall be provided in instructions for use. Information shall also be provided as marking on the equipment and on the label of the equipment, if appropriate.

4.12.2 Symbols

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

EN 980, EN ISO 9687, EN 60601-1, EN 60601-2-22, EN 60825-1.

4.12.3 Marking

Dental equipment shall be directly marked to identify the product and, if applicable, in accordance with the relevant standard. Marking shall include the following minimum information:

a) name or registered trade mark and address of the manufacturer. For dental equipment 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) trade name, or model 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;

e) the words "exclusively for clinical investigation", if the dental equipment is intended for clinical investigations;

f) connection details necessary for use with power sources;

g) warnings about hazards;

h) identification of operating controls.

4.12.4 Label

The label on the packing case or box shall include the following minimum information:

a) name or trade name and address of the manufacturer. For dental equipment 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 dental equipment;

c) batch code, preceded by the word "LOT" or the symbol LOT, or the serial number preceded by SN;

d) the words "exclusively for clinical investigation", if the equipment is intended for clinical investigations;

e) special storage and/or handling conditions.

4.12.5 Detachable components

If components of dental equipment are detachable they shall be identifiable, if appropriate, to enable them to be traced to the original item.

4.12.6 Instructions for use

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

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

a) details referred to in 4.12.3 and 4.12.4 with the exception of 4.12.3 d) and 4.12.4 c);

b) intended purpose of the dental equipment 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 equipment is intended to be connected to or used in combination with other devices;

d) relevant information for the safe and correct installation including connections to supply services and other items of equipment;

e) nature and frequency of service and calibration, if appropriate;

f) methods of cleaning, maintenance, disinfection and/or sterilization;

g) details of the nature, type, intensity and distribution of radiation and any protective measures to be taken in the case of devices emitting radiation for medical purposes;

h) characteristics and technical factors known to the manufacturer that could pose a hazard if the dental equipment was to be re-used;

i) date of issue of the instructions for use;

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

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	
4.2.4	7.5, 7.6	
4.3	8.1	
4.4.1	9.1, 9.2	
4.4.2	9.3	
4.5.1	11.1, 11.2	
4.5.2	11.3, 11.4	
4.6	12.1, 12.2, 12.3	
4.7	12.1.a	
4.8	12.6	
4.9.1	12.7.1	
4.9.2	12.7.2	
4.9.3	12.7.3	
4.9.4	12.7.4	
4.9.5	12.7.5	
4.10	12.9	
4.11	6.a	
4.12.1	13.1	
4.12.2	13.2	
4.12.3	13.3	
4.12.4	13.4	
4.12.5	13.5	
4.12.6	13.4, 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] ISO/TS 22595-1, *Dentistry — Plant area equipment — Part 1: Suction systems*

[6] ISO/TS 22595-2, *Dentistry — Plant area equipment — Part 2: Compressor systems*

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