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I.S. EN 1640:2009

Dentistry - Medical devices for dentistry - Equipment

I.S. EN 1640:2009

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

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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 19 September 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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

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 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)*