

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 It supersedes BS EN 1639:2004 which is withdrawn.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.

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Instruments

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde -
Instrumente

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Contents

	page
Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	7
4 Requirements	8
4.1 General.....	8
4.2 Chemical and physical properties	8
4.2.1 General.....	8
4.2.2 Contaminants and residues.....	8
4.2.3 Contact with substances	9
4.3 Control of contamination	9
4.3.1 General.....	9
4.3.2 Instruments supplied sterile.....	9
4.3.3 Instruments supplied non-sterile	9
4.4 Construction and environmental properties.....	9
4.5 Instruments connected to or equipped with an energy source.....	10
4.6 Protection against electrical risks	10
4.7 Protection against mechanical and thermal risks.....	10
4.7.1 Vibration	10
4.7.2 Noise	10
4.7.3 Electricity, gas or hydraulic and pneumatic energy	10
4.7.4 Surface temperature.....	10
4.8 Controls and indicators	11
4.9 Clinical evaluation	11
4.10 Marking, labelling and information supplied by the manufacturer	11
4.10.1 General.....	11
4.10.2 Symbols	11
4.10.3 Marking	11
4.10.4 Label.....	12
4.10.5 Detachable components	12
4.10.6 Instructions for use	12
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	14
Bibliography	15

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of an identical text or by endorsement, at the latest by April 2010, and conflicting national standards shall be withdrawn at the latest by April 2010.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