

Dentistry — Medical devices for dentistry — Equipment

The European Standard EN 1640:2004 has the status of a
British Standard

ICS 11.060.20

National foreword

This British Standard is the official English language version of EN 1640:2004. It supersedes BS EN 1640:1997 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/106, Dentistry, to Subcommittee CH/106/6, Dental equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

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 does not of itself confer immunity from legal obligations.

This British Standard, was published under the authority of the Standards Policy and Strategy Committee on 11 June 2004

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 12, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

BSI 11 June 2004

ISBN 0 580 43916 X

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 17 March 2004.

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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

	page
Foreword.....	3
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 Requirements	6
4.1 General.....	6
4.2 Chemical and physical properties	6
4.2.1 Materials	6
4.2.2 Contaminants and residues.....	6
4.2.3 Contact with substances	6
4.2.4 Ingress and leaking of substances	7
4.3 Control of contamination	7
4.4 Construction and environmental properties.....	7
4.5 Protection against radiation	7
4.6 Equipment connected to or equipped with an energy source	7
4.7 Protection against electrical risks	7
4.8 Protection against mechanical and thermal risks	8
4.8.1 Mechanical stability	8
4.8.2 Vibration	8
4.8.3 Noise	8
4.8.4 Electricity, gas, hydraulic and pneumatic energy	8
4.8.5 Surface temperature	8
4.9 Controls and indicators	8
4.10 Marking, labelling and information supplied by the manufacturer	8
4.10.1 General.....	8
4.10.2 Symbols	9
4.10.3 Marking	9
4.10.4 Labelling	9
4.10.5 Detachable components	9
4.10.6 Instructions for use	9
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	11
Bibliography	12

Foreword

This document (EN 1640:2004) 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 December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document supersedes EN 1640:1996.

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 relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.