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STANDARD

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**DENTISTRY - MEDICAL DEVICES FOR  
DENTISTRY - INSTRUMENTS**

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## Dentistry - Medical devices for dentistry - Instruments

Art dentaire - Dispositifs médicaux pour l'art dentaire -  
Instruments

Zahnheilkunde - Medizinprodukte für die Zahnheilkunde -  
Instrumente

This European Standard was approved by CEN on 17 March 2004.

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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 Central Secretariat has the same status as the official versions.

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## Foreword

This document (EN 1639:2004) 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of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.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 1639:1996.

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.

## 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: Particular 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 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 standard should be used in conjunction with EN 1640, which is applicable for dental equipment. This 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.

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