



**SLOVENSKI STANDARD**  
**SIST EN ISO 11499:2007**

**01-september-2007**

**BUKca Yý U**  
**SIST EN ISO 11499:2000**

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**Zobozdravstvo - Ampule z lokalnim anestetikom za enkratno uporabo (ISO 11499:2007)**

Dentistry - Single-use cartridges for local anaesthetics (ISO 11499:2007)

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**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.060.20	Z[ à[ c @ ã } æ ] ! ^ { æ	Dental equipment

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**en**

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English Version

Dentistry - Single-use cartridges for local anaesthetics (ISO  
11499:2007)

Art dentaire - Cartouches à usage unique pour  
anesthésiques locaux (ISO 11499:2007)

Zahnheilkunde - Zylinderampullen für Lokalanästhetika zum  
Einmalgebrauch (ISO 11499:2007)

This European Standard was approved by CEN on 30 June 2007.

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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 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.

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## Foreword

This document (EN ISO 11499:2007) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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of an identical text or by endorsement, at the latest by January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN ISO 11499:1999.

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.

### Endorsement notice

The text of ISO 11499:2007 has been approved by CEN as a EN ISO 11499:2007 without any modification.

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**Dentistry — Single-use cartridges for  
local anaesthetics**

*Art dentaire — Cartouches à usage unique pour anesthésiques locaux*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11499 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 11499:1997), which has been technically revised. The following changes have been made:

- a) introduction of a colour coding system for the concentration of the anaesthetic agent in single-use cartridges for local anaesthetics;  
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- b) introduction of a colour coding system for the concentration of the vasoconstrictor in single-use cartridges for local anaesthetics.

## Introduction

The safe and efficient operation of dental cartridges for local anaesthetics depends on their freedom from leakage, the control of the forces required to initiate and maintain the plunger movement and the absence of large air bubbles.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

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