



SLOVENSKI STANDARD

SIST EN ISO 11499:2014

01-oktober-2014

Nadomešča:
SIST EN ISO 11499:2007

Zobozdravstvo - Ampule z lokalnim anestetikom za enkratno uporabo (ISO 11499:2014)

Dentistry - Single-use cartridges for local anaesthetics (ISO 11499:2014)

Zahnheilkunde - Zylindrampullen für Lokalanästhetika zum Einmalgebrauch (ISO 11499:2014)

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Médecine bucco-dentaire - Cartouches à usage unique pour anesthésiques locaux (ISO 11499:2014)

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Ta slovenski standard je istoveten z: EN ISO 11499:2014

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.060.01	Zobozdravstvo na splošno	Dentistry in general

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EUROPEAN STANDARD

EN ISO 11499

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 11499:2007

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Dentistry - Single-use cartridges for local anaesthetics (ISO 11499:2014)

Médecine bucco-dentaire - Cartouches à usage unique pour anesthésiques locaux (ISO 11499:2014)

Zahnheilkunde - Zylinderampullen zum Einmalgebrauch für Lokalanästhetika (ISO 11499:2014)

This European Standard was approved by CEN on 22 May 2014.

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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-CENELEC Management Centre has the same status as the official versions.

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

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

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Foreword

This document (EN ISO 11499:2014) 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 December 2014, and conflicting national standards shall be withdrawn at the latest by December 2014.

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 ISO 11499:2007.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11499:2014 has been approved by CEN as EN ISO 11499:2014 without any modification.

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INTERNATIONAL
STANDARD

ISO
11499

Third edition
2014-06-01

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

*Médecine bucco-dentaire — Cartouches à usage unique pour
anesthésiques locaux*

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ISO 11499:2014(E)**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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 11499:2007), which has been technically revised. The following changes have been made:

- a) introduction of smaller cartridges of volume 1,0 ml and 1,7 ml;
- b) change in force for leakage test.

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 test methods for demonstrating freedom from unacceptable biological hazard are not included in this International Standard, but it is recommended that, for the assessment of possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

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