



NSAI
Standards

Irish Standard
I.S. EN ISO 11499:2014

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

I.S. EN ISO 11499:2014

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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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EN ISO 11499:2014 (E)

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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of an identical text or by endorsement, at the latest by December 2014, and conflicting national standards shall be withdrawn at the latest by December 2014.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.

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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*



Reference number
ISO 11499:2014(E)

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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.

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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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.

Dentistry — Single-use cartridges for local anaesthetics

1 Scope

This International Standard gives specific performance requirements for single-use dental cartridges of 1,0 ml, 1,7 ml, 1,8 ml and 2,2 ml nominal capacity for use with local anaesthetics.

It specifies tests for leakage, plunger movement, extractable volume and underfilling, and lists general overall dimensions to ensure that the cartridge will fit dental cartridge syringes complying with ISO 9997 and ISO 21533.

Labelling requirements are also specified.

NOTE A list of International Standards for certain types of cartridge component is given in the Bibliography.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 7885, *Dentistry — Sterile injection needles for single use*

ISO 9997, *Dental cartridge syringes*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 21533, *Dentistry — Reusable cartridge syringes intended for intraligamentary injections*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

cartridge for local anaesthetics

device containing local anaesthetics designed for use with dental cartridge syringes

3.2

effective length of the cartridge

the distance travelled by the plunger that expels the extractable volume

3.3

extractable volume

volume of anaesthetic solution which can be delivered when the cartridge is used with a dental cartridge syringe and a dental injection needle

4 Requirements

4.1 Freedom from leakage of anaesthetic solution

The filled cartridge shall be free from leakage of anaesthetic solution.

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