

Dentistry - Cartridge syringes (ISO 9997:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 9997:2020 sisaldab Euroopa standardi EN ISO 9997:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 9997:2020 consists of the English text of the European standard EN ISO 9997:2020.
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English Version

Dentistry - Cartridge syringes (ISO 9997:2020)

Médecine bucco-dentaire - Seringues pour cartouches
(ISO 9997:2020)

Zahnheilkunde - Ampullenspritzen (ISO 9997:2020)

This European Standard was approved by CEN on 21 January 2020.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 9997:2020) 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of an identical text or by endorsement, at the latest by August 2020, and conflicting national standards shall be withdrawn at the latest by August 2020.

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

This document supersedes EN ISO 9997:1999.

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

Endorsement notice

The text of ISO 9997:2020 has been approved by CEN as EN ISO 9997:2020 without any modification.

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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 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 9997:1999), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the normative references have been updated;
- the requirement for reprocessing has been added in [5.5](#);
- the tolerance for plunger rod movement has been tightened in [6.6](#).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Cartridge syringes

1 Scope

This document specifies requirements and test methods for cartridge syringes used in dentistry. These syringes are of the non-aspirating, aspirating and self-aspirating types using cartridges with dental local anaesthetics.

This document is not applicable to cartridge syringes having a mechanical-advantage action for creating high pressure.

This document specifies requirements for cartridge syringes with ISO metric thread sizes. However, attention is drawn to the existence of a variety of syringes with imperial thread sizes (see [Annex A](#)).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 261, *ISO general purpose metric screw threads — General plan*

ISO 965-1, *ISO general purpose metric screw threads — Tolerances — Part 1: Principles and basic data*

ISO 1942, *Dentistry — Vocabulary*

ISO 11499, *Dentistry — Single-use cartridges for local anaesthetics*

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

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 11499 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

aspiration

process by which blood or body fluid is drawn into an anaesthetic cartridge

3.2

cartridge

container for local anaesthetics