

Dentistry - Sterile injection needles for single use

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 7885:2010 sisaldab Euroopa standardi EN ISO 7885:2010 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.03.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.02.2010.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 7885:2010 consists of the English text of the European standard EN ISO 7885:2010.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.03.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 15.02.2010.

The standard is available from Estonian standardisation organisation.

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English Version

**Dentistry - Sterile injection needles for single use (ISO
7885:2010)**

Médecine bucco-dentaire - Aiguilles stériles pour injection,
non réutilisables (ISO 7885:2010)

Zahnheilkunde -Sterile Injektionskanülen zum
Einmalgebrauch (ISO 7885:2010)

This European Standard was approved by CEN on 20 January 2010.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 7885:2010) 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of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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 7885:2000.

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Endorsement notice

The text of ISO 7885:2010 has been approved by CEN as a EN ISO 7885:2010 without any modification.

Introduction

This International Standard is closely related to ISO 7864. Requirements for validated sterilization processes are described in International Standards prepared by ISO/TC 198, *Sterilization of health care products*. (See references [6] to [8] in Bibliography.)

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1, ISO 10993-11 and ISO 7405.

This International Standard specifies requirements for dental injection needles with metric sizes only. However, attention is drawn to the existence of dental injection needles with imperial threads (see Annex A).

Dentistry — Sterile injection needles for single use

1 Scope

This International Standard gives dimensional and performance requirements for sterile injection needles for single use which are used in dental cartridge syringes complying with ISO 9997 for injection of dental local anaesthetics. It further specifies requirements with respect to their packaging, labelling and colour coding. It does not cover needles for special applications or techniques.

Only the materials used for the construction of the needle tubing are specified.

2 Normative references

The following referenced documents are indispensable for the application 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 1942, *Dentistry — Vocabulary*

ISO 6009:1992, *Hypodermic needles for single use — Colour coding for identification*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 9997, *Dental cartridge syringes*

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

3 Terms and definitions

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

3.1

needle unit

primary container, needle and hub

See Figure 1.