

**Steriilsed ühekordselt kasutatavad
stomatoloogilisteks süsteteks
ettenähtud nõelad**

Sterile dental injection needles for single use

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 7885:2001 sisaldab Euroopa standardi EN ISO 7885:2000 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 18.05.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 7885:2001 consists of the English text of the European standard EN ISO 7885:2000.</p> <p>This document is endorsed on 18.05.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>Käesolev standard esitab nõuded selliste süsteteks ettenähtud steriilsete ühekordselt kasutatavate nõelte mõõtmetele ja ekspluatatsioonile, mida kasutatakse stomatoloogilistes püstolsüstaldes lokaalsete anesteetikumide (paiksete tuimastite) manustamiseks. Standard ei hõlma eriotstarbeliseks kasutamiseks ja erivõteteks ette nähtud nõelu.</p>	<p>Scope:</p>
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Võtmesõnad: anesteesia, hambaraviaparatuur, jõudlus, mõõtmed, nõelad nahaalusteks süsteteks, pärast kasutamist hävitatavad vahendid, sildiga märgistamine, steriilne varustus, stomatoloogia, stomatoloogilised süstepüstolid, tehnilised andmed

English version

**Sterile dental injection needles for single use
(ISO 7885 : 2000)**

Aiguilles dentaires stériles pour
injection, non réutilisables
(ISO 7885 : 2000)

Sterile zahnärztliche Injektionskanülen
zum einmaligen Gebrauch
(ISO 7885 : 2000)

This European Standard was approved by CEN on 2000-12-15.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 7885 : 2000 Sterile dental injection needles for single use, which was prepared by ISO/TC 106 'Dentistry' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 7885 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative.)

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*.

In some countries national pharmacopoeia or other legally binding regulations may take precedence over this International Standard.

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). Manufacturers currently producing needles with imperial thread sizes are requested to change to ISO metric threads; the year 2005 has been set as a target date.

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 and ISO 7405.

1 Scope

This International Standard gives dimensional and performance requirements for sterile, single-use injection needles for dental cartridge syringes for injection of dental local anaesthetics. It does not cover needles for special applications or techniques.

Materials of construction other than those of the needle tubing are not specified.

This International Standard does not give requirements for validated sterilization processes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of IEC and ISO maintain registers of currently valid International Standards.

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

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

ISO 7864:1993, *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 manufacture of medical devices*.

ISO 9997, *Dental cartridge syringes*.

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

needle unit

the primary container, needle and hub

See Figure 1.