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

I.S. EN ISO 7885:2010

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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)

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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of an identical text or by endorsement, at the latest by August 2010, and conflicting national standards shall be withdrawn at the latest by August 2010.

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This document supersedes EN ISO 7885:2000.

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

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I.S. EN ISO 7885:2010
**INTERNATIONAL
STANDARD**

**ISO
7885**

Third edition
2010-02-15

**Dentistry — Sterile injection needles for
single use**

*Médecine bucco-dentaire — Aiguilles stériles pour injection, non
réutilisables*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 7885 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 7885:2000), which has been technically revised as follows:

- a) deletion of requirement for patency of lumen;
- b) introduction of colour coding for smaller needle size 0,2;
- c) updated labelling requirements.

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.

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