SLOVENSKI STANDARD
SIST EN ISO 7864:2000

01-januar-2000

Sterilne podkožne igle za enkratno uporabo (ISO 7864:1993)

Sterile hypodermic needles for single use (ISO 7864:1993)

Sterile Einmal-Injektionskanülen (ISO 7864:1993)

Aiguilles hypodermiques stériles, non réutilisables (ISO 7864:1993)

Ta slovenski standard je istoveten z: **EN ISO 7864:1995**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 7864:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7864

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Descriptors: See ISO document

English version

Sterile hypodermic needles for single use (ISO 7864:1993)

Aiguilles hypodermiques stériles, non réutilisables (ISO 7864:1993)

Sterile Einmal-Injektionskanülen (ISO 7864:1993)

This European Standard was approved by CEN on 1995-10-28. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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

CEN

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

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

The text of the International Standard from ISO/TC 84 "Medical devices for injections" of the International Organization for Standardization (ISO) has been taken over as a European Standard by the Technical Committee CEN/TC 205 "Non-active medical devices".

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of an identical text or by endorsement, at the latest by June 1996, and conflicting national standards shall be withdrawn at the latest by June 1996.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 7864:1993 has been approved by CEN as a European Standard without any modification.

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

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993
ISO 3696	1987	Water for analytical use - Specification and test methods	EN ISO 3696	1995
ISO 6009	1992	Hypodermic needles for single use - colour coding for identification	EN 26009	1994
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times	EN 28601	1992
ISO 9626	1991	Stainless steel needle tubing for the manufacture of medical devices	EN ISO 9626	1995

INTERNATIONAL STANDARD

ISO 7864

Third edition
1993-05-15

Sterile hypodermic needles for single use

Aiguilles hypodermiques stériles, non réutilisables

Reference number
ISO 7864:1993(E)

Contents

Annexes

International Organization for Standardization
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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.

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.

International Standard ISO 7864 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This third edition cancels and replaces the second edition (ISO 7864:1988), of which it constitutes a technical revision.

The major differences between this edition and the 1988 edition are as follows.

a) This International Standard specifies the use of needle tubing complying with ISO 9626. As requirements for metallic materials, stiffness, resistance to breakage and resistance to corrosion are given in ISO 9626, they have been deleted from this International Standard. The preparation of ISO 9626 has also allowed the introduction of new, smaller outside diameters of needle tubing and of tubing of thin- and extra-thin-walled types into this International Standard. In order to avoid inhibiting innovation, this International Standard no longer recommends combinations of needle diameter and length.

b) Additional information and guidance have been introduced on needle point geometry and fragmentation properties, and the limited number of tests for toxicity given in the 1988 edition has been replaced by an informative annex that lists a significantly greater number of relevant biological tests.

c) This International Standard permits the use on package labelling of the ISO symbol for "do not re-use", but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

Annex A forms an integral part of this International Standard. Annexes B, C and D are for information only.

Introduction

This International Standard covers sterile hypodermic needles intended for single use primarily in humans.

This International Standard does not give requirements or test methods for freedom from biological hazard because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological tests relevant to hypodermic needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the needles are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Plastics materials to be used for the construction of needles are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids included in relevant pharmacopoeiae.

Hypodermic needles specified in this International Standard are intended for use with hypodermic syringes specified in ISO 595 and ISO 7886-1. They will also fit syringes of types 1 and 2 specified in ISO 8537.

In some countries, national pharmacopoeiae or government regulations are legally binding and their requirements may take precedence over this International Standard.

Sterile hypodermic needles for single use

1 Scope

This International Standard specifies requirements for sterile hypodermic needles for single use of nominal outside diameters 0,3 mm and 1,2 mm.

It does not apply to dental needles.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

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

ISO 7886-1:—[1], *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

3 Nomenclature

The nomenclature for components of hypodermic needles for single use is shown in figure 1 together with the designation for length *l*; nomenclature for needle points is shown in figure 2.

4 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter.

When examined under × 2,5 magnification, the hub socket shall appear free from particles and extraneous matter.

5 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that of the control fluid.

6 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption

1) To be published.