Steriilsed nahaalusteks süsteteks ettenähtud ühekordselt kasutatavad nõelad

Sterile hypodermic needles for single use

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 7864:1999 sisaldab Euroopa standardi EN ISO 7864:1995 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 7864:1999 consists of the English text of the European standard EN ISO 7864:1995. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standard esitab nõuded steriilsetele nahaalusteks süsteteks ettenähtud ühekordselt kasutatavatele nõeltele. Standard ei kehti stomatoloogiliste nõelte kohta.	**Scope:**

ICS 11.040.20

Võtmesõnad: meditsiiniaparatuur, mõõtmed, nõelad nahaalusteks süsteteks, pakendamine, sildiga märgistamine, tehnilised andmed, testimine, tähistus, värvusmärgistus

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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 and is identical to the ISO Standard as referred to.

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.

This European Standard exists 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

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Foreword

International Standard

ISO 7864:1993 Sterile hypodermic needles for single use,

which was prepared by ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices' 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 1996 at the latest.

In accordance with 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 United Kingdom.

Endorsement notice

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

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

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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.

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.