# Steriilsed nahaalusteks süsteteks ettenähtud ühekordselt kasutatavad süstlad.Osa 1: Süstlad käsitsi süstimiseks

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use

**EESTI STANDARDI EESSÕNA** **NATIONAL FOREWORD**

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| Käesolev Eesti standard EVS-EN ISO 7886-1:1999 sisaldab Euroopa standardi EN ISO 7886-1:1997 ingliskeelset teksti.<br><br>Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.<br><br>Standard on kättesaadav Eesti standardiorganisatsioonist. | This Estonian standard EVS-EN ISO 7886-1:1999 consists of the English text of the European standard EN ISO 7886-1:1997.<br><br>This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation.<br><br>The standard is available from Estonian standardisation organisation. |

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| **Käsitlusala:**<br>Standardi käesolev osa esitab nõuded steriilsetele ühekordselt kasutatavatele nahaalusteks süsteteks ettenähtud süstaldele, mis on valmistatud plastist ning ette nähtud vedelike aspireerimiseks või vedelike süstimiseks kohe pärast täitmist. | **Scope:** |

**ICS** 11.040.20

**Võtmesõnad:** meditsiiniaparatuur, mõõtmed, pakendamine, pärast kasutamist hävitatavad vahendid, sildiga märgistamine, süstlad, tehnilised andmed, testimine

# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

EN ISO 7886-1

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Descriptors: Medical equipment, syringes for single use.



**English version**

## Sterile hypodermic syringes for single use

Part 1: Syringes for manual use

(ISO 7886-1 : 1993, including Technical Corrigendum 1 : 1995)

Seringues hypodermiques stériles, non réutilisables – Partie 1: Seringues pour utilisation manuelle (ISO 7886-1 : 1993, Rectificatif Technique 1 : 1995 inclus)

Sterile Einmalspritzen für medizinische Zwecke – Teil 1: Spritzen zum manuellen Gebrauch (ISO 7886-1 : 1993, einschließlich Technische Korrektur 1 : 1995)

This European Standard was approved by CEN on 1997-02-28.

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.

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CEN

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

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

## Foreword

International Standard

ISO 7886-1 : 1993 Sterile hypodermic syringes for single use – Part 1: Syringes for manual 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', the Secretariat of which is held by BSI, 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 November 1997 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 7886-1 : 1993, including Technical Corrigendum 1 : 1995 was approved by CEN as a European Standard without any modification.

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

## Contents

## Introduction

This part of ISO 7886 does not give requirements or test methods for freedom from biological hazard. Guidance on biological tests relevant to hypodermic syringes 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 syringes are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Materials to be used for the construction of syringes 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. Guidance on some aspects of the selection of materials is given in annex E.

The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling the primary container. It is not practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in annex F. These test methods can be regarded only as a means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. The types of material that have received wide acceptance are included in annex E. If an incompatibility exists, the injection should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers.

Hypodermic syringes specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

This part of ISO 7886 does not cover syringes for the injection of insulin (see ISO 8537).

In some countries, national pharmacopoeia or government regulations are legally binding and their requirements may take precedence over this part of ISO 7886.

## 1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials and intended for the aspiration of fluids or for the injection of fluids immediately after filling.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes with needles permanently attached, syringes for use with power-driven syringe pumps, syringes pre-filled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist.

NOTE 1 A second part of ISO 7886 is being prepared to cover syringes for use with power-driven syringe pumps.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7886. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7886 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 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

## 3 Definitions

For the purposes of this part of ISO 7886, the following definitions apply.

**3.1 nominal capacity:** Capacity of the syringe as designated by the manufacturer.

NOTE 2 Examples are 1 ml, 5 ml, 50 ml.

**3.2 graduated capacity:** Volume of water at (20 ± 5) °C [or, for tropical countries (27 ± 5) °C] expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals.

**3.3 total graduated capacity:** Capacity of the syringe at the graduation line furthest from the zero graduation line.

NOTE 3 The total graduated capacity may be equal to, or greater than, the nominal capacity.

**3.4 maximum usable capacity:** Capacity of the syringe when the piston is drawn back to its furthest functional position.

**3.5 fiducial line:** Line circumscribing the end of the piston for determining the capacity corresponding to any scale reading of the syringe.

## 4 Nomenclature

The nomenclature for components of hypodermic syringes for single use is shown in figure 1.