# Steriilsed nahaalusteks süsteteks ettenähtud ühekordselt kasutatavad süstlad. Osa 3: Fikseeritud doosiga immuniseerimiseks mõeldud automaatselt kasutuskõlbmatuks muutuvad süstlad

Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization

EESTI STANDARDIKESKUS
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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| Käesolev Eesti standard EVS-EN ISO 7886-3:2009 sisaldab Euroopa standardi EN ISO 7886-3:2009 ingliskeelset teksti. | This Estonian standard EVS-EN ISO 7886-3:2009 consists of the English text of the European standard EN ISO 7886-3:2009. |
| Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. |
| Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 23.09.2009. | Date of Availability of the European standard text 23.09.2009. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |

**ICS** 11.040.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 7886-3

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Supersedes EN ISO 7886-3:2005

English Version

## Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)

Seringues hypodermiques stériles, non réutilisables - Partie 3: Seringues autobloquantes pour vaccination à dose fixe (ISO 7886-3:2005)

Sterile Einmalspritzen für medizinische Zwecke - Teil 3: Selbstblockierende Spritzen für die Injektion mit fixer Impfstoffdosis (ISO 7886-3:2005)

This European Standard was approved by CEN on 24 August 2009.

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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 CEN Management Centre has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**



Ref. No. EN ISO 7886-3:2009: E

# Foreword

The text of ISO 7886-3:2005 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7886-3:2009.

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 March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 7886-3:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

**Endorsement notice**

The text of ISO 7886-3:2005 has been approved by CEN as a EN ISO 7886-3:2009 without any modification.

# Annex ZA
(informative)

## Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices**

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| 5 | 1, 7.1, 7.2, 7.5 | E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed. |
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| 8 | 1, 7.1, 7.2, 7.5 | E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed. |
| 9 | 10.1, 10.3 | |
| 10 | 1, 10.1, 10.2, 10.3 | |
| 11.1 | 1, 10.1, 10.2 | |
| 11.2 | 10.2 | |
| 12.1 | 1, 2, 3, 10.2, 12.8.2 | |
| 12.2 | 1, 2, 3, 12.8.1, 12.8.2 | |
| 12.3 | 10.2 | |
| 13.1 | 1, 2 | |

**Table ZA.1 (continued)**

| Clause(s)/sub-clause(s) of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | |
|---|---|---|
| 13.2 | 1, 2, 9.1 | |
| 14.1 | 1, 2, 10.1, 10.3 | |
| 14.2 | 1, 2, 7.5, 7.6 | |
| 14.3 | 1, 2, 3, 12.8.2, 8.1 | |
| 14.4 | 5 | |
| 15.1 | 3, 7.2, 8.3, 8,7 | |
| 15.2 | 7.2, 8.3, 8,7 | |
| 16 | 13.1, 13.2, 13.3, 13.4, 13.5, 13.6 | Except 13.3 (f) (second phrase regarding indication of single use consistent across community),<br>except 13.3 (a) (regarding representative in the Community),<br>except 13.6 (h) – 2nd phrase (information on known characteristics and technical factors known to manufacturer that could pose a risk if reused) and 13.6 (q) (regarding date of issue or latest revision of instructions for use) |
| NOTE | 6 a | Requirement on clinical evaluation not covered by this standard |

**WARNING —** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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# Introduction

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this third part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of fixed dose immunization syringes in the developing and transitional countries. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens.

The World Health Organization had produced a specification for syringes that are rendered inactive after use (commonly referred to as “auto-disable” syringes). Both the WHO and ISO agreed that an additional part of ISO 7886 would be required to cover “auto-disable” syringes, whilst leaving in place ISO 7886 Parts 1 and 2 without modification, as a large number of devices in common use would not be intended to comply with the auto-disable properties suggested.

This part of ISO 7886 is intended to cover “fixed dose” immunization syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by Parts 1 and 2 of ISO 7886.

It is recognized that syringes designed to reduce the risk of needlestick injuries, in addition to preventing sharps injuries, may also comply with this part of ISO 7886 with regard to their auto-disable properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

# Sterile hypodermic syringes for single use —

# Part 3:
# Auto-disable syringes for fixed-dose immunization



## 1 Scope

This part of ISO 7886 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic materials and stainless steel and intended for the aspiration of vaccines or for the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine, the syringe is automatically rendered unusable.

This part of ISO 7886 does not specify the design of the auto-disable feature, which is left to the discretion of the manufacturer.

This part of ISO 7886 is not applicable to syringes for use with insulin (specified in ISO 8537), syringes made of glass (specified in ISO 595), syringes for use with power-driven syringe pumps (specified in ISO 7886-2), auto-disable syringes for variable dose delivery and syringes designed to be prefilled. It does not address compatibility with injection fluids/vaccines.

NOTE A fourth part of ISO 7886 is being prepared to cover syringes with reuse prevention feature.

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

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:1991, *Sterile single-use syringes, with or without needle, for insulin*

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

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*