Steriilsed nahaalusteks süsteteks ettenähtud ühekordselt kasutatavad süstlad. Osa 4: Korduskasutuse välistatusega süstlad

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 7886-4:2009 sisaldab Euroopa standardi EN ISO 7886-4:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7886-4:2009 consists of the English text of the European standard EN ISO 7886-4:2009.
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.

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English Version

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empêchant la réutilisation (ISO 7886-4:2006)

Sterile Einmalspritzen für medizinische Zwecke - Teil 4: Spritzen mit Vorrichtung zur Verhinderung der Wiederverwendung (ISO 7886-4:2006)

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 7886-4:2006 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 7886-4:2009.

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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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 7886-4:2006.

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 7886-4:2006 has been approved by CEN as a EN ISO 7886-4:2009 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
6	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.
7	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.
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	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.
10	10.1, 10.3	
11	1, 10.1, 10.2, 10.3	
11.1	1, 10.1, 10.2, 10.3	
11.2	1, 10.1, 10.2,	
11.3	10.1	
12	10.1, 10.2	
12.1	10.1, 10.2	
12.2	1, 9, 2, 10.2	

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
13.1	1 – 9.2 1, 2, 3, 10.2, 12.8.2	
13.2	1 – 9.2, 1, 2, 3 , 10.2, 12.8.2	
13.3	10.2	
14.1	1, 2	
14.2	1, 2, 9.1	
15.1	1, 2, 10.1, 10.3	
15.2	7.5 – 10.1	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.
15.3	1 - 2 - 8.1	
15.4	5	
15.5	7.1	Only guidance is given
16.1	7.2, 8.3	
16.2	7.2, 8.3	
17	13.1	
17.2.1 a)	13.2 – 13.3 f	Except 13.3 (f) (second phrase regarding indication of single use consistent across community)
17.2.1 b)	13.2	
17.2.1 c)	13.3 a	Except 13.3 (a) (regarding representative in the Community)
17.2.1 d)	13.2 – 13.3 c	
17.2.1 e)	13.2 – 13.3 d	
17.2.1 f)	13.2 – 13.3 e	
17.2.1 g)	13.3 b	
17.2.2 a)	13.2 – 13.3 f	Except 13.3 (f) (second phrase regarding indication of single use consistent across community)
17.2.2 b)	13.2	
17.2.2 c)	13.3 a	Except 13.3 (a) (regarding representative in the Community)
17.2.2 d)	13.2 – 13.3 c	
17.2.2 e)	13.2 – 13.3 d	
17.2.2 f)	13.2 – 13.3 e	
17.2.2 g)	13.3 b	
17.3 a)	13.2 – 13.3 f	Except 13.3 (f) (second phrase regarding indication of single use consistent across community)

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
17.3 b)	13.2	
17.3 c)	13.3 a	Except 13.3 (a) (regarding representative in the Community)
17.3 d)	13.2 – 13.3 c	
17.3 e)	13.2 – 13.3 d	
17.3 f)	13.2 – 13.3 e	
17.3 g)	13.3 b	
17.3 h)	13.3 k	
17.3 i)	13.3 k	
17.3 j)	13.3 i	
17.3 k)	13.6	Except 13.6 (h) – 2nd phrase NA, feature to prevent re-use is part of the design and except 13.6 (q) (regarding date of issue or latest revision of instructions for use)
17.3 l)	13.3 b	
17.4 a)	13.3 b	
17.4 b)	13.2	
17.4 c)	13.2 – 13.3 d	
17.4 d)	13.2 – 13.3 e	
17.4 e)	13.2 – 13.3 c	
17.4 f)	13.3 a	Except 13.3 (a) (regarding representative in the Community)
17.4 g)	13.3 i	
17.4 h)	13.3 b	
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

The preparation of this part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of 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. See Reference [1] in the Bibliography.

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

This part of ISO 7886 is intended to cover syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by ISO 7886-1 and ISO 7886-3. ISO 7886-2 covers syringes used with power-driven pumps. Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention is to be considered for each specific intended use.

It is recognized that syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention 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 4:
Syringes with re-use prevention feature

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This part of ISO 7886 is not applicable to syringes made of glass (specified in ISO 595), auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this part of ISO 7886.

NOTE Syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

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 780, *Packaging — Pictorial marking for handling of goods*

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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*