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STERIILSED ÜHEKORDSED SÜSTLAD NAHAALUSTEKS SÜSTETEKS. OSA 1: SÜSTLAD KÄSITSI KASUTAMISEKS

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:2017, Corrected version 2019-08)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

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See Eesti standard EVS-EN ISO 7886-1:2018 sisaldab Euroopa standardi EN ISO 7886-1:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7886-1:2018 consists of the English text of the European standard EN ISO 7886-1:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.03.2018.	Date of Availability of the European standard is 28.03.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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ICS 11.040.25

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7886-1

March 2018

ICS 11.040.25

Supersedes EN ISO 7886-1:1997

English Version

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:2017, Corrected version 2019-08)

Seringues hypodermiques stériles, non réutilisables - Partie 1: Seringues pour utilisation manuelle (ISO 7886-1:2017, Version corrigée 2019-08)

Sterile Einmalspritzen für medizinische Zwecke - Teil 1: Spritzen zum manuellen Gebrauch (ISO 7886-1:2017)

This European Standard was approved by CEN on 28 February 2017.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 09 October 2019.

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO 7886-1:2018 E

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European foreword

This document (EN ISO 7886-1:2017) has been prepared by Technical Committee ISO/TC 84 " Devices for administration of medicinal products and catheters " in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 September 2018, and conflicting national standards shall be withdrawn at the latest by September 2018.

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

This document supersedes EN ISO 7886-1:1997.

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(s).

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

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	**ISO or IEC**
ISO 15223-1:2016	EN ISO 15223-1:2016	ISO 15223-1:2016
ISO 23908	EN ISO 23908:2013	ISO 23908:2011
ISO 80369-7	EN ISO 80369-7:2017	ISO 80369-7:2016

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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Endorsement notice

The text of ISO 7886-1:2017, Corrected version 2019-08 has been approved by CEN as EN ISO 7886-1:2018 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/295 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
7.3	6.2	Standard Clause 6.2 meets ER 7.3 in respect of the device altering the pH of the contents of the device.
7.5	13.2	Standard Clause 13.2 covers ER 7.5 only in respect of leakage past the plunger.
7.6	14.1.1, 14.1.2	Standard Clause 14.1.1 meets ER 7.6 in respect of packaging only. Standard Clause 14.1.2 meets the ER 7.6 up to the point of use.

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Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
8.3	14.1.1, 14.1.2	
9.2	5, 6, 10, 11	Standard Clauses 5, 6, 10 and 11 meet ER 9.2 for the aspects detailed in the Standard Clauses.
10.1	8, 9.4, 11.2	Standard Clause 8 meets ER 10.1 except for the last sentence. Standard Clauses 9.4 and 11.2 meet the requirements of ER 10.1 as they relates to the relationship between the zero graduation line of the scale and the fiducial line on the plunger stopper only.
10.2	9.1, 9.2	
10.3	15.2.1 b)	
13.1	15	
13.3 (a)	15.2.2 b), 15.3 f), 15.4.1 b), 15.5 e)	
13.3 (b)	15.3 e), 15.4.1 e), 15.5 f), 15.6 a)	
13.3 (c)	15.3 a), 15.4.2 a), 15.5 a), 15.5 b), 15.6 c)	
13.3 (d)	15.3 c), 15.4.1 c), 15.5 d), 15.6 b)	
13.3 (e)	15.3 g), 15.4.1 f), 15.5 g), 15.6 f)	
13.3 (f)	15.2.2 a), 15.3 b), 15.4.1 a), 15.5 c)	
13.3 (i)	15.6 e)	
13.3 (k)	15.4.2 b)	

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical committee ISO/TC 84, *Devices for administration of medicinal products and catheters.*

This second edition cancels and replaces the first edition (ISO 7886-1:1993), which has been technically revised. It also incorporates the Technical corrigendum ISO 7886-1:1993/Cor.1:1995.

The main changes to the previous edition are the following:

a) clarified the Scope, e.g. excluding single-use syringes made of glass;

b) added new Normative references;

c) added new terms and definitions;

d) clarified the drawing to illustrate the component of the syringe;

e) included general requirements;

f) revised test methods for syringes;

g) revised the labelling requirement;

h) clarified the type of lubricant for the different types of syringes;

i) replaced Annex E (informative): Examples of test methods for incompatibility between syringes and injection fluids with Annex E (informative): Test method for the determination of forces required to operate the piston;

j) added Annex F (informative): Test method for the quantity of silicone;

k) informative annex on materials has been deleted.

A list of all parts in the ISO 7886 series can be found on the ISO website.

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This corrected version of ISO 7886-1:2017 incorporates the following corrections:

— In the key to Figure E.1, item 2 was corrected to read "needle [1,2 mm (18 G) and approximately 40 mm length";

— In the key to Figure E.1, item 3 was corrected to read " tubing [(2,7 ± 0,1) mm i.d. and (500 ± 5) mm in length with male and female Luer adapters at each end)]";

— In E.2.3, the value "(19,5 ± 0,5) cm" was changed to "(500 ± 5) mm".

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