BSI Standards Publication

Sterile hypodermic syringes for single use

Part 1: Syringes for manual use

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 7886-1:2018. It is identical to ISO 7886-1:2017. It supersedes BS EN ISO 7886-1:1997, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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30 June 2018	Implementation of CEN correction notice 18 April 2018: Title and supersession details of European Foreword corrected
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EUROPEAN STANDARD **EN ISO 7886-1**

NORME EUROPÉENNE

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English Version

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO 7886-1:2017)

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

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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 7886-1:2018 E

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of an identical text or by endorsement, at the latest by *September 2018*, and conflicting national standards shall be withdrawn at the latest by *September 2018*.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.

Endorsement notice

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

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.

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.

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".

Introduction

The ISO 7886 series covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as not to limit innovation and methods of packaging. Its appearance and layout are consistent with other related standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in this document. Several limits for requirements which are historic based but confirmed in practice for many years have been kept.

Materials to be used for the construction and lubrication of sterile syringes for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers. 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 on unit packaging. It is not practicable to specify a universally acceptable test method for incompatibility, as the only conclusive test is that an individual specific injection fluid is compatible 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. If an incompatibility is identified, the injection fluid 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 of injectable preparations.

Syringes should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

The sampling plans for inspection selected for the ISO 7886 series are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems requirements that appear in standards on quality systems, for example the ISO 9000 series and ISO 13485.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of syringes.

Guidance on transition periods for implementing the requirements of ISO 7886 (all parts) is given in ISO/TR 19244.

INTERNATIONAL STANDARD ISO 7886-1:2017(E)

Sterile hypodermic syringes for single use —

Part 1:
Syringes for manual use

1 Scope

This document specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users. This document does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this document are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit for filling by a pharmacist).

Hypodermic syringes without a needle specified in this document are intended for use with hypodermic needles specified in ISO 7864.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
nominal capacity
capacity of the syringe as designated by the manufacturer

EXAMPLE 1 ml, 5 ml, 50 ml