BS EN ISO 7864:2016

BSI Standards Publication

Sterile hypodermic needles for single use — Requirements and test methods (ISO 7864:2016)

bsi.

This British Standard is the UK implementation of EN ISO 7864:2016. It supersedes BS EN ISO 7864:1996 which is withdrawn.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.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Date	Text affected

EUROPEAN STANDARD **EN ISO 7864**

NORME EUROPÉENNE

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ICS 11.040.25 Supersedes EN ISO 7864:1995

English Version

Sterile hypodermic needles for single use - Requirements and test methods (ISO 7864:2016)

Aiguilles hypodermiques stériles, non réutilisables - Exigences et méthodes d'essai (ISO 7864:2016)

Sterile Injektionskanülen für den Einmalgebrauch - Anforderungen und Prüfverfahren (ISO 7864:2016)

This European Standard was approved by CEN on 15 July 2016.

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

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 7864:2016) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" 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of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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 7864:1995.

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 ISO or IEC standard, as listed in Table 1.

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

Table 1— Correlations between undated 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 594-1	EN 20594-1: 1993/AC: 1996/ A1: 1997	ISO 594-1:1986
ISO 594-2	EN 1707:1996	ISO 594-2:1998
ISO 3696	EN ISO 3696:1995	ISO 3696:1987
ISO 6009	EN ISO 6009:1994/AC:2008	ISO 6009:2016
ISO 8601	--	ISO 8601: 2004
ISO 9626	EN ISO 9626:1995/A1:2001	ISO 9626:2016
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2009
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 23908	EN ISO 23908::2013	ISO 23908:2011
ISO 80369-1	EN ISO 80369-1:2010	ISO 80369-1:2010
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7864:2016 has been approved by CEN as EN ISO 7864:2016 without any modification.

Annex ZA
(informative)

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

This European Standard has been prepared under a Commission's standardization 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 160].

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)/sub-clause(s) of this EN	Remarks/Notes
7.1	4.9.1, 4.9.4, 4.14	
7.3	4.4, 4.5, 4.9.1, 4.9.4, 4.14	
7.5	4.4, 4.5, 4.9.1, 4.9.4, 4.14	The part of ER 7.5 related to phthalates is not explicitly covered.
7.6	4.8.1	
8.1	4.14, 5	The part of ER 8.1 relating to easy handling is not addressed.
8.3	5	
8.4	4.14.1, 5.1	
9.1	4.8.1	
9.2	4.6, 4. 9.3, 4.9.4, 4.10	

13.1	6.1	
13.2	4.7, 4.8.2, 4.9, 6.2, 6.3	
13.3(a)	6.2(e), 6.3(g), 6.4(e)	
13.3(b)	6.2(a), 6.3(a), 6.4(a)	
13.3 (c)	6.2(b), 6.3(b), 6.4(c)	
13.3(d)	6.2(c), 6.3(e),6.4(b)	
13.3(e)	6.2 (f), 6.3(f), 6.4(d)	
13.3 (f)	6.2(d), 6.3(c)	
13.3(i)	6.3(h), 6.4(f)	
13.3(k)	6.1, 6.3(d)	

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 products falling within the scope of this standard.

Contents

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

In some countries, national regulations are legally binding and their requirements take precedence over the ones in this International Standard.

This fourth edition cancels and replaces the third edition (ISO 7864:1993), which has been technically revised with the following changes:

a) expansion of the range of gauges;

b) introduction of tapered needle designation;

c) reference to the new ISO 80369- series;

d) new informative annex on penetration force;

e) change in Annex B on fragmentation;

f) deleted informative Annex C for symbol for "do-not-reuse" and added normative reference to ISO 15223-1;

g) new informative annex on flow rate;

h) new informative annex on needle bonding strength;

i) reference to ISO 23908 on sharps injury protection.

Introduction

This International Standard covers sterile hypodermic needles for single use intended to inject or withdraw fluids from primarily the human body.

Plastics materials to be used for the construction of needles 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.

Hypodermic needles specified in this International Standard are intended for use with syringes having a 6 % Luer conical fitting as specified in ISO 80369-7 in conjunction with ISO 80369-1 and ISO 80369-20.

Devices/connectors intended to mate with hypodermic needles of the standard, but which deviate from ISO 80369-7 shall provide demonstrated evidence of safe functional performance.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

Sterile hypodermic needles for single use — Requirements and test methods

1 Scope

This International Standard specifies requirements for sterile hypodermic needles for single use of designated metric sizes 0,18 mm to 1,2 mm.

It does not apply to those devices that are covered by their own standard such as dental needles and pen needles.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1[1)], *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

ISO 594-2[2)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

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

ISO 6009, *Hypodermic needles for single use Colour coding for identification*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

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

1) Upon its publication, ISO 80369-7 will replace ISO 594-1.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2.