BS EN ISO 8537:2016

BSI Standards Publication

Sterile single-use syringes, with or without needle, for insulin

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National foreword

This British Standard is the UK implementation of EN ISO 8537:2016. It supersedes BS EN ISO 8537:2008 which is withdrawn.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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8537

April 2016

ICS 11.040.20

Supersedes EN ISO 8537:2008

English Version

Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2016)

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille (ISO 8537:2016)

Sterile Insulin-Einmalspritzen mit oder ohne Kanüle (ISO 8537:2016)

This European Standard was approved by CEN on 27 February 2016.

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European foreword

This document (EN ISO 8537:2016) 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of an identical text or by endorsement, at the latest by October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.

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 8537:2008.

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.

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.

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.

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Table — 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 594-1	EN ISO 594-1:1986	ISO 594-1:1986
ISO 7864	EN ISO 7864:1995*	ISO 7864:1993*
ISO 9626	EN ISO 9626:1995*	ISO 9626:1991*
ISO 14971	EN ISO 14971:2012	ISO 14971
ISO 62366-1	EN ISO 62366-1:2015	IEC 62366-1:2015
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 10993-1	EN ISO 10993-1:2009	ISO 10993-1:2003
ISO 80369-7	EN ISO 80369-7:2016**	ISO 80369-7:2016**

* New versions expected end of 2015.

** Expected 2016.

Endorsement notice

The text of ISO 8537:2016 has been approved by CEN as EN ISO 8537:2016 without any modification.

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Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/EEC

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 the Essential Requirements of Directive 93/42/EEC.

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 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 Directive 93/42/EEC

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.1 m	7.1	
6.1.2 c, 6.1.3 c, 6.2 b	7.2	
5.2, 5.4	7.3	
5.11.2, 5.11.3	7.5	
6.1	7.6	
6.1.2, 6.1.3, 7.2.2, 7.3, 7.4	8.3	
5.1 n	8.4	
5.1, 5.4, 5.6, 5.7, 7.3 g, 7.4 h, 7.5 h, 7.6 f	9.2	
5.1 e, 5.1 g	10.1	
5.1 e, 5.2	10.2	
5.1 f	10.3	

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Clause 7	13.1	
Clause 7	13.2	
7.2.1, 7.2.2, 7.3, 7.4, 7.5, 7.6, 7.7	13.3	
7.2.1 b, 7.3 e, 7.4 g	13.4	
7.4, 7.5, 7.6	13.6	The information is provided on the packaging and no additional instruction for use is required

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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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*.

This third edition cancels and replaces the second edition (ISO 8537:2007), which has been technically revised to include the following changes:

a) revised the introduction;

b) revised the scope to include various concentrations of insulin, specified plastic materials and excluded, e.g. single-use syringes made of glass;

c) added some normative references;

d) added new definitions;

e) added new colour codes for higher concentration of insulin;

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

g) included general requirements;

h) revised test methods for syringes;

i) revised the labelling requirement;

j) moved the syringe sizes and graduated scales in Annex H;

k) deleted Annex I.

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Introduction

This International Standard covers insulin syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as to not limit innovation in technology or methods of packaging. Its appearance and layout are consistent with other TC 84 International Standards, which are designed to be more performance-based than design-prescriptive.

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

This edition introduces general requirements as design guidelines for manufacturers. This edition retains a number of limits on requirements, which were originally based on consensus opinion but subsequently have been confirmed in practice.

This International Standard does not specify materials to be used for the construction and lubrication of sterile insulin syringes and needles for single use because their selection will depend, to some extent, upon the manufacturer's specific syringe design, process of manufacture, and sterilization method.

Insulin syringes and needles are to be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

This International Standard emphasizes the importance of having individual syringes that are appropriately graduated and labelled for only one concentration of insulin. Serious problems can result if a syringe is used with a concentration of insulin that is different from the one for which it was designed. Hazards associated with dosing errors with highly concentrated insulin (U300 and U500) are considered higher than the experience with U40 and U100.

It is preferred that when more than one insulin concentration is in a market, the new concentration be provided in a dedicated delivery system that make miss-dosing less likely.

In acknowledgement that insulin in higher concentrations in vials are available in some markets, new formulations are under development and dedicated delivery systems other than syringes are not always appropriate for all markets, this International Standard introduces new colour codes to differentiate syringes for the new higher concentrations of insulin.

The sampling plans for inspection selected for this International Standard 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 that appear in standards on quality systems, for example, the ISO 9000 series and ISO 13485.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244, developed by ISO/TC 84.

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INTERNATIONAL STANDARD ISO 8537:2016(E)

Sterile single-use syringes, with or without needle, for insulin

1 Scope

This International Standard specifies requirements and test methods for empty, sterile, single-use syringes, with or without needles, made of plastic materials and intended solely for the injection of insulin, with which the syringes are filled by the end user. This International Standard covers syringes intended for single-use only in humans and with insulins of various concentrations.

The insulin syringes specified in this International Standard are intended for use (i.e. insulin injection) immediately after filling and are not intended to contain insulin for extended periods of time.

This International Standard excludes single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes that are pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit intended for filling by a pharmacist).

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

ISO 7864, *Sterile hypodermic needles for single use*

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

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

ISO 11608–1, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 11608–5, *Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions*

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

ISO 15223-1:2012, *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 catheter and needles used for blood sampling*

ISO/IEC 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications (under development)*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

1) To be replaced by ISO 80369–7.

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