



DPC: 25/30498371 DC

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Date: 01 December 2025

Origin: International

Latest date for receipt of comments: 24 January 2026

Project No. 2024/02231

Responsible committee: CH/84 Catheters and syringes

Interested committees:

Title: Draft BS EN ISO 8537 Sterile single-use syringes, with or without needle, for insulin.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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Submission of Comments

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- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 8537

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

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille

ICS: 11.040.25

ISO/TC 84

Secretariat: **DS**

Voting begins on:
2025-12-01

Voting terminates on:
2026-02-23

This document is circulated as received from the committee secretariat.

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ISO/DIS 8537:2025(en)

Full document details: 25/30498371 DC

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Published in Switzerland

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 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 fourth edition cancels and replaces the third edition (ISO 8537:2016), which has been technically revised.

The main changes are as follows:

— xxx xxxxxxxx xxx xxxxx

Drafting note: New list to be developed by WG 11.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document 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 ISO/TC 84 documents, 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 document 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 will be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

This document emphasises 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 (U200, U300 and U500) are more severe than 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 mis-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 document introduces new colour codes to differentiate syringes for the new higher concentrations of insulin.

The sampling plans for inspection selected for this document 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 quality management systems, e.g. ISO 9001 or ISO 13485.

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

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

1 Scope

This document 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 document covers syringes intended for single-use only in humans and with insulins of various concentrations.

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

This document 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 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 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 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 23908, *Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods*

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

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

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

dead space

volume of liquid left in the syringe and needle, where supplied with the syringe, when the plunger is fully depressed during normal use

3.2

fiducial line

leading edge of the *plunger stopper* (3.11), which is in contact with and perpendicular to the syringe barrel and aligns with the zero marking on the syringe barrel when the piston is fully inserted

3.3

graduated capacity

scale interval or intervals in graduation line

3.4

multiple-unit packaging

package containing more than one self-contained syringe

3.5

needle cap

cover intended to protect physically the needle tube prior to use

3.6

needle length

usable length of needle

Note 1 to entry: Needle length is shown in [Figure 1](#).

3.7

nozzle cap

sheath intended to protect physically the needle hub prior to use

3.8

piston

assembled component of plunger and *plungerstopper* (3.11)

3.9

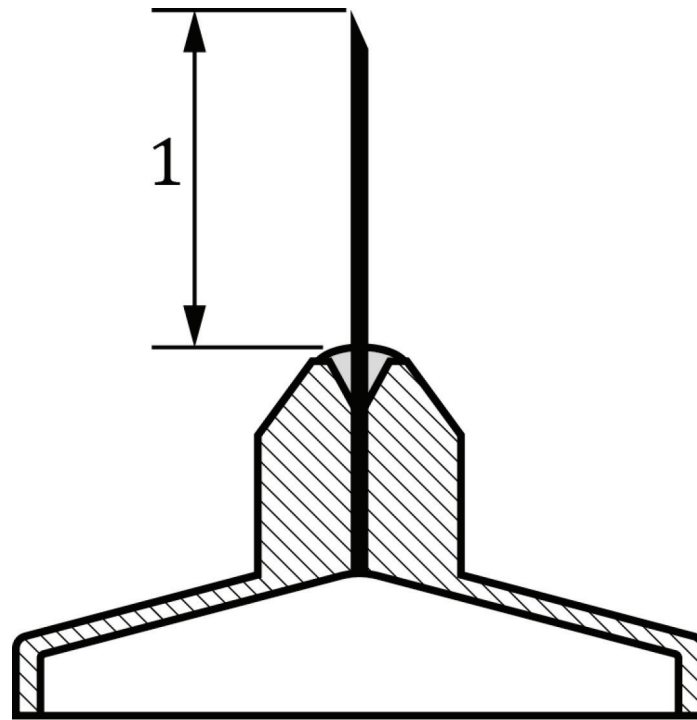
plunger cap

cover intended to maintain the sterility of the syringe and to enclose the projecting portion of the plunger and push button, if present

3.10

plunger delivery

device mechanism which advances the *plungerstopper* (3.11) to deliver the medicinal product

**Key**

1 needle length

Figure 1 — Needle length

3.11**plunger stopper**

component connected to the leading end of the plunger and seals the open end of the syringe barrel

3.12**self-contained syringe**

syringe with protective end caps intended to maintain the sterility of the interior of the syringe until one of the caps is removed

Note 1 to entry: Protective end caps may be *plunger cap* (3.9), *nozzle cap* (3.7) or *needle cap* (3.5).

3.13**total graduated capacity**

capacity of the syringe at the graduation line farthest from the zero graduation line

Note 1 to entry: The total graduated capacity may be equal to, or greater than, the nominal capacity.

3.14**unit packaging**

package containing a single syringe, with or without a needle, which maintains the sterility of the contents until the package is opened

3.15**user packaging**

packaging which contains one or more items of unit packaging or self-contained syringes or multiple-unit packaging, but is not intended to maintain sterility of the contents

4 Nomenclature

The type of syringe shall be designated as follows (see also [Figure 2](#)):

- **Type 1**; syringe having a 6 % (Luer) male conical fitting, supplied with no needle and packaged in unit packaging.
- **Type 2**; syringe having a 6 % (Luer) male conical fitting, supplied with no needle and fitted with protective plunger and nozzle caps and packaged.
- **Type 3**; syringe having a 6 % (Luer) male conical fitting and supplied with a detached or detachable needle and packaged in a unit packaging.
- **Type 4**; syringe having a 6 % (Luer) male conical fitting and supplied with a detachable needle and fitted with protective plunger and needle caps and packaged.
- **Type 5**; syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and packaged in a unit packaging.
- **Type 6**; syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and fitted with protective caps and packaged.
- **Type 7**; syringe with fixed needle tube and packaged in a unit packaging.
- **Type 8**; syringe with fixed needle tube and fitted with protective end caps and packaged.