

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

The European Standard EN ISO 8537:1994, with the incorporation of amendment A1:2000, has the status of a British Standard

ICS: 11.040.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/2, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Clinical Pathologists
- British Diabetic Association
- British Glass Manufacturers' Confederation
- British Surgical Trades Association
- Department of Health
- Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
- Medical Sterile Products Association
- Royal Pharmaceutical Society of Great Britain

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 28 February 1992

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Amendments issued since publication

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 8537:1991, including amendment 1:2000, *Sterile single-use syringes, with or without needle, for insulin*, published by the International Organization for Standardization (ISO).

In 1994 the European Committee for Standardization (CEN) accepted ISO 8537:1991 as European Standard EN ISO 8537:1994. As a consequence of implementing the European Standard this British Standard is renumbered as BS EN ISO 8537:1995 and any reference to BS 7548 should be read as a reference to BS EN ISO 8537.

Attention is drawn to the specification for reusable syringes for insulin injection given in BS 1619-1:1962 and BS 1619-2:1988.

Syringes should be manufactured and sterilized in accordance with the recommendations in the “Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products”¹⁾.

Attention is drawn to the fact that, although this British Standard covers syringes for use with insulin of strengths 40 units/ml (U-40) and 100 units/ml (U-100), only U-100 insulin is normally used in the UK.

Attention is drawn to the Manufacturer’s Registration Scheme administered by the Department of Health.

It is British Standard practice to present recommendations and guidance in the form of notes and appendices. The International Standard contains recommendations, expressed by the use of the auxiliary verb “should”, in the main text. In order to comply with this standard users have only to comply with the requirements expressed by the auxiliary verb “shall”.

Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to ii, the EN ISO title page, pages 2 to 20, an inside back cover and a back cover.

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¹⁾ Compiled by the Department of Health and Social Security; published by and available from HMSO, 49 High Holborn, London WC1 for personal callers or by post from HMSO, PO Box 276, London SW8 5DT.

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English version

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

(includes amendment A1:2000)

(includes (ISO 8537:1991 + A1:2000))

Seringues à insuline stériles non réutilisables
avec ou sans aiguille
(inclut l'amendement A1:2000)
(ISO 8537:1991 + A1:2000)

Sterile Insulin-Einmalspritzen mit oder ohne
Kanüle
(enthält Änderung A1:2000)
(ISO 8537:1991 + A1:2000)

This European Standard was approved by CEN on 1994-07-27.
Amendment A1:2000 was approved by CEN on 2000-11-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been taken over by the Technical Committee CEN/TC 205, Non-active medical devices, from the work of ISO/TC 84, Medical devices for injections, of the International Organization for Standardization (ISO).

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 January 1995, and conflicting national standards shall be withdrawn at the latest by January 1995.

According to CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

NOTE Normative references to international publications are listed in Annex ZA (normative).

Foreword to amendment A1

The text of this amendment EN ISO 8537:1994/A1:2000 to the EN ISO 8537:1994 from Technical Committee ISO/TC 84, Medical devices for injections, of the International Organization for Standardization (ISO) has been taken over as an amendment to the European Standard by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This amendment to the European Standard EN ISO 8537:1994 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2001, and conflicting national standards shall be withdrawn at the latest by May 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This International Standard deals with products primarily intended for use with humans and provides performance requirements, but permits some variations of design and of the methods of packaging and sterilization by individual manufacturers.

Materials to be used for the construction and lubrication of sterile syringes and needles 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.

Syringes and needles should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices, and should be free from defects affecting appearance, safety and serviceability for their intended use.

Certain grades of polypropylene, polystyrene and styrene/acrylonitrile copolymer have been extensively used for the barrels of sterile syringes for single use. A high quality natural rubber composition is frequently used for the piston, although other materials such as silicone rubber are also used, the surface of the piston being lubricated with polydimethylsiloxane. For 2 ml syringes, high density polyethylene is frequently used for the seal of the two-component design of syringe in combination with a polypropylene barrel containing a fatty acid amide slip additive.

When selecting materials the following should be considered.

- **Clarity of barrel:** Materials used in the construction of the wall of the syringe barrel should be of sufficient clarity to enable dosages to be read without difficulty and for air bubbles to be seen.
- **Compatibility with insulin preparations:** The materials of syringes and needles (including lubricant) and packaging should not, in their final form after sterilization and under conditions of normal use, detrimentally affect the efficacy, safety and acceptability of insulin preparations: neither should the construction materials be themselves affected physically or chemically by insulin preparations.
- **Biocompatibility:** The materials should not cause the syringes and needles to yield, under conditions of normal use, significant amounts of toxic substances and should permit them to satisfy the appropriate national requirements or regulations for freedom from pyrogenic materials and abnormal toxicity. For testing these properties, an extract as specified in Annex H may be used.

It is strongly recommended that regulatory authorities, pharmacopoeiae and relevant trade associations should recognize the need for further testing, especially for incompatibility between the insulins and syringes when they are in contact for prolonged periods.

In some countries national regulations are legally binding and their requirements may take precedence over this International Standard.

This International Standard describes syringes with or without needles for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100). It is recommended that syringes graduated for only one strength of insulin be used in each country to avoid accidents. For those countries using more than one strength of insulin, the importance of having individual syringes appropriately graduated for only one strength of insulin as specified in this International Standard is emphasized. Serious problems may result if a syringe is used with a strength of insulin for which it is not designed. If the syringe is used for mixing different types of insulin, it is strongly recommended that the procedure is performed in the same order each time.

1 Scope

This International Standard specifies requirements and test methods for sterile syringes with or without needles intended for single use solely for the injection of insulin and primarily in humans. It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100).

Sterile syringes specified in this International Standard are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*.

ISO 7864:1988, *Sterile hypodermic needles for single use*.

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

3 Definitions and nomenclature

For the purposes of this International Standard, the following definitions apply. The nomenclature of some components of syringes for single use is given in Figure 1.

3.1

graduated capacity

volume of water at $20\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$ or $27\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$ expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals

3.2

needle cap

protective end cap intended to maintain the sterility of the needle tube and to protect physically the needle tube and needle hub, if present

3.3

needle sheath

cover intended to provide physical protection to the needle tube

3.4

protective end caps

covers intended to enclose the projecting portion of the plunger and push-button at one end and the nozzle and/or the needle at the other end