SLOVENSKI STANDARD
SIST EN ISO 8537:2008

01-september-2008

Nadomeġļa:
SIST EN ISO 8537:2000
SIST EN ISO 8537:2000/A1:2001

Sterilne injekcijske brizge za insulin za enkratno uporabo, z iglo ali brez nje (ISO 8537:2007)

Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2007)

Sterile Insulin-Einmalspritzen mit oder ohne Kanüle (ISO 8537:2007)

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille (ISO 8537:2007)

Ta slovenski standard je istoveten z: **EN ISO 8537:2008**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 8537:2008 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8537

July 2008

ICS 11.040.25

Supersedes EN ISO 8537:1994

English Version

Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2007)

Seringues à insuline, stériles, non réutilisables, avec ou sans aiguille (ISO 8537:2007)

Sterile Insulin-Einmalspritzen mit oder ohne Kanüle (ISO 8537:2007)

This European Standard was approved by CEN on 15 June 2008.

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

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Contents

Page

Foreword

The text of ISO 8537:2007 has been prepared by Technical Committee ISO/TC 84 “Medical devices for injections” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8537:2008 by 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of an identical text or by endorsement, at the latest by January 2009, and conflicting national standards shall be withdrawn at the latest by January 2009.

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.

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Endorsement notice

The text of ISO 8537:2007 has been approved by CEN as a EN ISO 8537:2008 without any modification.

INTERNATIONAL STANDARD

ISO 8537

Second edition
2007-10-01

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

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

Reference number
ISO 8537:2007(E)

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8537 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 8537:1991) and its Amendment 1 (ISO 8537:1991/Amd.1:2000), which have been technically revised.

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, make the following considerations:

— 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 themselves be 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, pharmacopoeia 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 the 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.