SLOVENSKI STANDARD
SIST EN ISO 8537:2000/A1:2001

01-november-2001

Sterilne injekcijske brizge za insulin za enkratno uporabo, z iglo ali brez nje (ISO 8537:1991/DAM 1:2000))

Sterile single-use syringes, with or without needle, for insulin (ISO 8537:1991/DAM 1:2000)

Sterile Insulin-Einmalspritzen mit oder ohne Kanüle (ISO 8537:1991/DAM 1:2000)

Seringues a insuline stériles non réutilisables avec ou sans aiguille (ISO 8537:1991/DAM 1:2000)

Ta slovenski standard je istoveten z: **EN ISO 8537:1994/A1:2000**

ICS:

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

SIST EN ISO 8537:2000/A1:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8537:1994/A1

November 2000

ICS 11.040.20

English version

Sterile single-use syringes, with or without needle, for insulin (ISO 8537:1991/DAM 1:2000)

Seringues à insuline stériles non réutilisables avec ou sans aiguille (ISO 8537:1991/DAM 1:2000)

Sterile Insulin-Einmalspritzen mit oder ohne Kanüle (ISO 8537:1991/DAM 1:2000)

This amendment A1 modifies the European Standard EN ISO 8537:1994; it was approved by CEN on 1 November 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This amendment 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 Management Centre 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 8537:1994/A1:2000 E

Foreword

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.

Endorsement notice

The text of the Amendment to the International Standard ISO 8537:1994/Amendment 1:2000 has been approved by CEN as an Amendment to the European Standard without any modification.

INTERNATIONAL STANDARD

ISO 8537

First edition
1991-05-01

AMENDMENT 1
2000-11-01

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

AMENDMENT 1

Seringues à insuline stériles non réutilisables avec ou sans aiguille

AMENDEMENT 1

Reference number
ISO 8537:1991/Amd.1:2000(E)

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Printed in Switzerland

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 3.

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 Amendment may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to International Standard ISO 8537:1991 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*.

Amendment 1 to ISO 8537:1991 was submitted to an ISO/CEN parallel enquiry in 1998, and aimed at taking into account shorter and thinner needles which are extensively used throughout the world, by modification of some clauses of ISO 8537. It relied on ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices*, which is under amendment to include the new sizes of needle tubing.

As the amendment of ISO 9626:1991 has been delayed, this amendment to ISO 8537 is independent of the text of ISO 9626. It is not applicable to needle tubing of 0,38 mm outside diameter because this size is not included in ISO 9626.

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

AMENDMENT 1

Page 1

Clause 2 Normative references

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

Definition 3.1

Change “gratuated” to “graduated”.

Page 5

Clause 13 Needles

Change the title to “**Needle tubing and needles**”. Delete the entire text, and substitute the following new text.

13.1 Needles for syringes of types 3 and 4

Needles for syringes of types 3 and 4 shall be in accordance with ISO 7864, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard.

13.2 Needle tubing for syringes of types 5, 6, 7 and 8

Needle tubing for syringes of types 5, 6, 7 and 8 shall be in accordance with ISO 9626, except for the dimensions and test parameters which shall be in accordance with annex D of this International Standard. The needle point shall be in accordance with ISO 7864.

NOTE ISO 9626:1991 is at present undergoing amendment; the values in annex D (see below) are taken from the most recent draft. Some values therefore differ from those given in ISO 7864:1993 and ISO 9626:1991. When the ISO 9626 amendment is published, clause 13 and annex D of this International Standard may be replaced by a normative cross-reference to ISO 7864 and amended ISO 9626.

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Annex D

Delete the entire annex D and substitute the following.