INTERNATIONAL STANDARD

ISO 8537

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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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Foreword

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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.

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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.

Annex D
(normative)

Properties of needles and needle tubing

D.1 The diameters of the needle tubing shall be in accordance with Table D.1.

Table D.1 — Diameters of needle tubing

Dimensions in millimetres

Nominal outside diameter [a]	Outside diameter		Minimum inside diameter
	min.	max.	
0,25	0,254	0,267	0,114
0,30	0,298	0,320	0,133
0,33	0,324	0,351	0,133
0,36	0,349	0,370	0,133
0,40	0,400	0,420	0,184
0,45	0,440	0,470	0,232

[a] The nominal outside diameters correspond to gauge numbers as follows: 0,25 mm (gauge 31), 0,30 mm (gauge 30), 0,33 mm (gauge 29), 0,36 mm (gauge 28), 0,40 mm (gauge 27) and 0,45 mm (gauge 26).

D.2 The stiffness of the needle tubing shall be in accordance with Table D.2 when tested as described in ISO 9626.

Table D.2 — Stiffness

Nominal outside diameter	Span mm ± 0,1	Force N ± 0,1	Maximum deflection mm
0,25	3,5	5,5	0,35
0,30	5,0	5,5	0,40
0,33	5,0	5,5	0,32
0,36	5,0	5,5	0,25
0,40	9,5	5,5	0,60
0,45	10,0	6,0	0,56

D.3 The minimum strength of the bond between the hub/syringe and the needle tubing shall be 22 N when tested in accordance with ISO 7864.

D.4 The stylet diameter to test the patency of the lumen as described in ISO 7864 shall be in accordance with Table D.3.

Table D.3 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter	Diameter of stylet $^{0}_{-0,01}$
0,25	0,08
0,30	0,11
0,33	0,11
0,36	0,11
0,40	0,15
0,45	0,18

D.5 The resistance to breakage shall be assessed in accordance with Table D.4 when tested as described in ISO 9626.

Table D.4 — Resistance to breakage

Dimensions in millimetres

Nominal outside diameter	Distance between rigid supports and application of bending force ± 0,1
0,25	8
0,30	8
0,33	8
0,36	8
0,40	8
0,45	10

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