INTERNATIONAL STANDARD

ISO 7864

Third edition
1993-05-15

Sterile hypodermic needles for single use

Aiguilles hypodermiques stériles, non réutilisables

Reference number
ISO 7864:1993(E)

Contents

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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.

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.

International Standard ISO 7864 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Sub-Committee SC 1, *Syringes, needles and intravascular catheters for single use*.

This third edition cancels and replaces the second edition (ISO 7864:1988), of which it constitutes a technical revision.

The major differences between this edition and the 1988 edition are as follows.

a) This International Standard specifies the use of needle tubing complying with ISO 9626. As requirements for metallic materials, stiffness, resistance to breakage and resistance to corrosion are given in ISO 9626, they have been deleted from this International Standard. The preparation of ISO 9626 has also allowed the introduction of new, smaller outside diameters of needle tubing and of tubing of thin- and extra-thin-walled types into this International Standard. In order to avoid inhibiting innovation, this International Standard no longer recommends combinations of needle diameter and length.

b) Additional information and guidance have been introduced on needle point geometry and fragmentation properties, and the limited number of tests for toxicity given in the 1988 edition has been replaced by an informative annex that lists a significantly greater number of relevant biological tests.

c) This International Standard permits the use on package labelling of the ISO symbol for "do not re-use", but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

Annex A forms an integral part of this International Standard. Annexes B, C and D are for information only.

Introduction

This International Standard covers sterile hypodermic needles intended for single use primarily in humans.

This International Standard does not give requirements or test methods for freedom from biological hazard because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological tests relevant to hypodermic needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the needles are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Plastics materials to be used for the construction of needles are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids included in relevant pharmacopoeiae.

Hypodermic needles specified in this International Standard are intended for use with hypodermic syringes specified in ISO 595 and ISO 7886-1. They will also fit syringes of types 1 and 2 specified in ISO 8537.

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

Sterile hypodermic needles for single use

1 Scope

This International Standard specifies requirements for sterile hypodermic needles for single use of nominal outside diameters 0,3 mm and 1,2 mm.

It does not apply to dental needles.

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 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 6009:1992, *Hypodermic needles for single use — Colour coding for identification.*

ISO 7886-1:—[1], *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

3 Nomenclature

The nomenclature for components of hypodermic needles for single use is shown in figure 1 together with the designation for length *l*; nomenclature for needle points is shown in figure 2.

4 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter.

When examined under × 2,5 magnification, the hub socket shall appear free from particles and extraneous matter.

5 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that of the control fluid.

6 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption

1) To be published.

method, an extract prepared in accordance with annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l.

7 Size designation

The size of hypodermic needle shall be designated by the following:

a) the nominal outside diameter of the needle tube, expressed in millimetres;

b) the nominal length of the needle tube, expressed in millimetres.

The size shall be referred to as "the designated metric size" and shall be expressed in millimetres.

EXAMPLE

0,8 × 40

8 Colour coding

The nominal outside diameter of hypodermic needles shall be identified by colour coding in accordance with ISO 6009 applied to the unit container and/or part of the needle assembly such as the needle hub or the sheath.

9 Needle hub

9.1 Conical fitting

The conical socket of the hypodermic needle hub shall be in accordance with ISO 594-1.

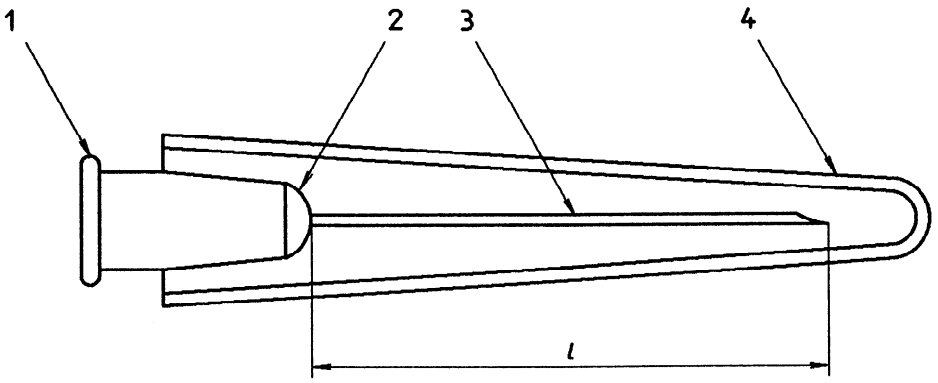
If the hub has a locking fitting, it shall be in accordance with ISO 594-2.

9.2 Colour of hub

The hub shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.

10 Sheath

If a separate needle sheath is provided, it shall be made either of pigmented or of unpigmented material. If pigmented, the colour shall be in accordance with ISO 6009.



Key

1 Hub
2 Jointing medium
3 Needle tube
4 Sheath

Figure 1 — Example of typical hypodermic needle and sheath for single use

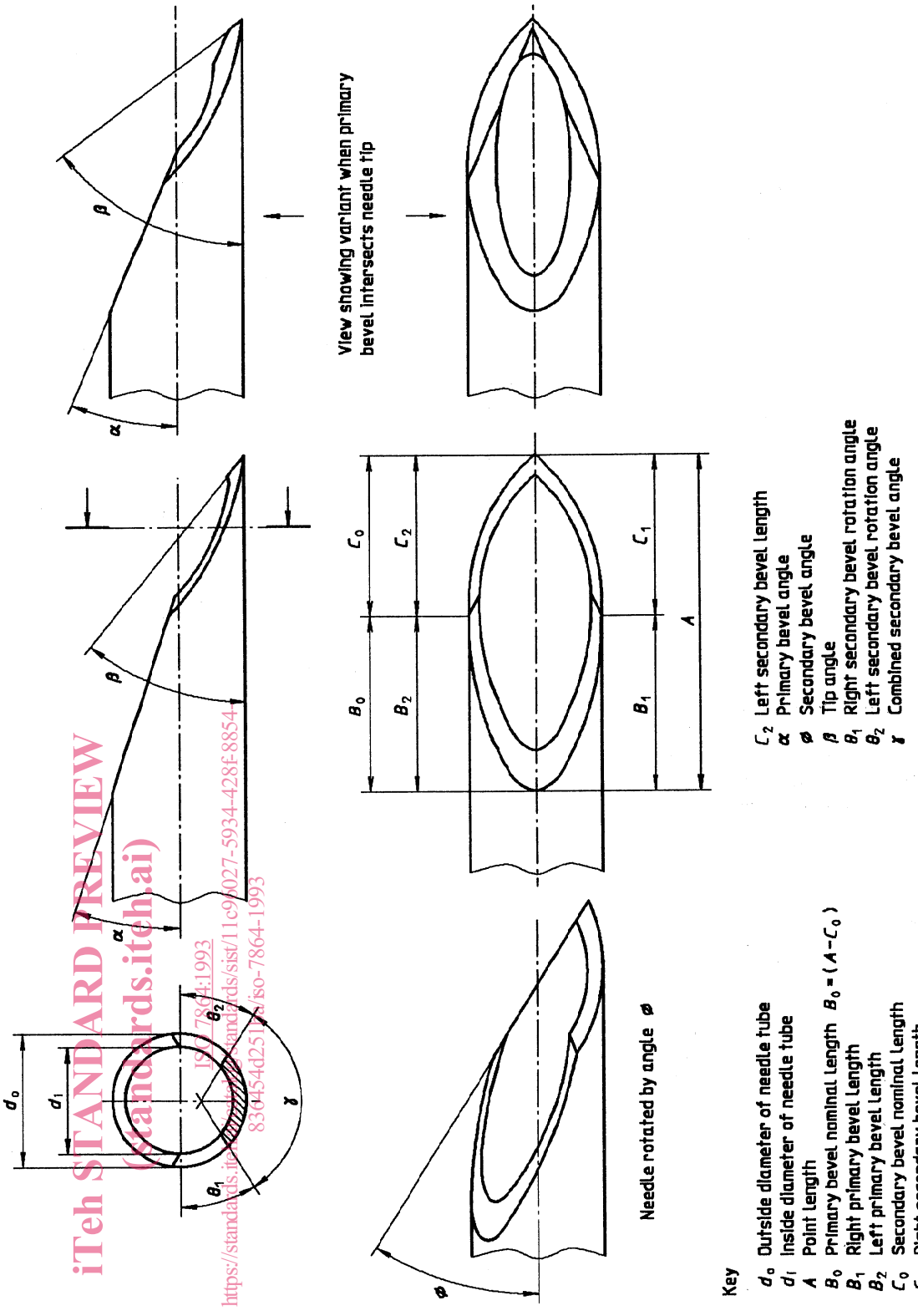


Figure 2 — Designation of dimensions and nomenclature of needle point geometry (see clause 12)

11 Needle tube

11.1 General

The needle shall be made of tubing in accordance with ISO 9626.

11.2 Tolerances on length

The actual length of the needle tube (see dimension *l* in figure 1) shall equal the nominal length within the tolerances given in table 1.

Table 1 — Tolerances on length of needle tube

Dimensions in millimetres

Nominal length of needle tube	Tolerance
< 25	$^{+1}_{-2}$
25 to 39	$^{+1,5}_{-2,5}$
40	$^{0}_{-4}$
> 40	$^{+1,5}_{-2,5}$

11.3 Freedom from defects

When examined by normal or corrected vision, the needle tube shall appear straight and of regular cross-section and wall thickness.

11.4 Lubricant

If the hypodermic needle tube is lubricated, the lubricant shall not be visible, under normal or corrected vision, as droplets of fluid on the outside or inside surfaces of the needle tube.

NOTE 1 An acceptable lubricant, applied undiluted, is polydimethylsiloxane complying with a national or the European pharmacopoeia. The quantity of lubricant used should not exceed 0,25 mg per square centimetre of the surface area of the needle tube.

12 Needle point

When examined under × 2,5 magnification, the needle point shall appear sharp and free from feather edges, burrs and hooks.

NOTE 2 The needle point usually has a bevel with a primary bevel angle of (11 ± 2)° (as illustrated in figure 2), but a "short" bevel with other angle, e.g. (17 ± 2)°, may be provided.

The designation of needle point dimensions and the nomenclature used to describe the dimensions and features is shown for information in figure 2. The needle points shown are of configurations commonly manufactured: other configurations may be equally satisfactory. It may not be necessary to use all the dimensions when describing the point configuration.

The needle point should be designed so as to minimize coreing and fragmentation when penetrating vial closures. This International Standard does not specify requirements or test methods for these properties, but an example of a test method for determining the production of fragments from rubber closures is given in annex B.

13 Performance

13.1 Bond between hub and needle tube

The union of the hub and needle tube shall not be broken by the minimum force given in table 2 applied as push or pull in the direction of the needle axis.

Table 2 — Force to test bond between hub and needle tube

Nominal outside diameter of needle mm	Force min. N
0,3	22
0,33	22
0,36	22
0,4	22
0,45	22
0,5	22
0,55	34
0,6	34
0,7	40
0,8	44
0,9	54
1,1	69
1,2	69

13.2 Patency of lumen

The patency of the lumen shall be such that either

a) a stainless steel stylet of the appropriate diameter selected from the diameters given in table 3 shall pass through the needle; or

b) the rate of flow of water through the needle under a hydrostatic pressure not exceeding

1×10^5 Pa[2)] shall be not less than 80 % of that of a needle of equivalent outside diameter and length having a minimum inside diameter in accordance with ISO 9626 when tested under the same pressure.

Table 3 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter of needle	Diameter of stylet $^{0}_{-0,01}$ for needle of normal-walled tubing	for needle of thin-walled tubing	for needle of extra-thin-walled tubing
0,3	0,11	0,13	—
0,33	0,11	0,15	—
0,36	0,11	0,15	—
0,4	0,15	0,19	—
0,45	0,18	0,23	—
0,5	0,18	0,23	—
0,55	0,22	0,27	—
0,6	0,25	0,29	0,30
0,7	0,30	0,35	0,37
0,8	0,40	0,42	0,44
0,9	0,48	0,49	0,50
1,1	0,58	0,60	0,68
1,2	0,70	0,73	0,83

14 Packaging

14.1 Primary container

Each hypodermic needle shall be sealed in a primary container. The material and design of this container shall be such as to ensure that the colour coding of the contents is visible.

The materials of the container should not have detrimental effects on the contents. The materials and design of this container should be such as to ensure

a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) the minimum risk of contamination of the contents during removal from the container;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.

14.2 Secondary container

One or more primary containers shall be packaged in a secondary container.

The secondary container should be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary containers may be packaged in a storage and/or a transit container.

15 Labelling

15.1 Primary container

The primary container shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with clause 7;

b) the word "STERILE";

c) the lot number, prefixed by the word "LOT";

d) the name or trade-mark or trade-name or logo of the manufacturer or supplier.

15.2 Secondary container

The secondary container shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with clause 7, the number, the type or angle of bevel (see clause 12) and, if appropriate, the words "thin-walled" or "extra-thin-walled" or equivalent or an abbreviation;

b) the word "STERILE";

c) the words "FOR SINGLE USE" or equivalent (excepting the term "disposable");

NOTE 3 The symbol given in annex C may additionally be given.

d) a warning to check the integrity of each primary container before use;

e) the lot number, prefixed by the word "LOT";

2) 1 standard atmosphere (atm) = 101 325 Pa

1 technical atmosphere (at) = 98 066,5 Pa