INTERNATIONAL STANDARD

ISO 7864

Fourth edition
2016-08-01

Sterile hypodermic needles for single use — Requirements and test methods

Aiguilles hypodermiques stériles, non réutilisables — Exigences et méthodes d'essai

Reference number
ISO 7864:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

In some countries, national regulations are legally binding and their requirements take precedence over the ones in this International Standard.

This fourth edition cancels and replaces the third edition (ISO 7864:1993), which has been technically revised with the following changes:

a) expansion of the range of gauges;

b) introduction of tapered needle designation;

c) reference to the new ISO 80369- series;

d) new informative annex on penetration force;

e) change in Annex B on fragmentation;

f) deleted informative Annex C for symbol for "do-not-reuse" and added normative reference to ISO 15223-1;

g) new informative annex on flow rate;

h) new informative annex on needle bonding strength;

i) reference to ISO 23908 on sharps injury protection.

Introduction

This International Standard covers sterile hypodermic needles for single use intended to inject or withdraw fluids from primarily the human body.

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.

Hypodermic needles specified in this International Standard are intended for use with syringes having a 6 % Luer conical fitting as specified in ISO 80369-7 in conjunction with ISO 80369-1 and ISO 80369-20.

Devices/connectors intended to mate with hypodermic needles of the standard, but which deviate from ISO 80369-7 shall provide demonstrated evidence of safe functional performance.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

Sterile hypodermic needles for single use — Requirements and test methods

1 Scope

This International Standard specifies requirements for sterile hypodermic needles for single use of designated metric sizes 0,18 mm to 1,2 mm.

It does not apply to those devices that are covered by their own standard such as dental needles and pen needles.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 594-2[2)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

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

ISO 6009, *Hypodermic needles for single use Colour coding for identification*

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

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

1) Upon its publication, ISO 80369-7 will replace ISO 594-1.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2.

3.1
gauge
legacy size designation; a particular gauge size corresponds to a designated metric size defining limits for outer diameters

3.2
unit packaging
packaging of an individual device, intended to maintain its sterility

3.3
user packaging
packaging, which contains one or more items of unit packaging, designed to provide labelling information to the user

3.4
needle cap
cover intended to physically protect the needle tube prior to use

3.5
tapered needle
needle with conical needle tube which has an outer diameter spanning at least two consecutive designated metric sizes

4 Requirements

4.1 General

Testing finished products shall be conducted on sterilized products.

4.2 Statistics and reproducibility of test methods

Any suitable test system can be used when the required accuracy (calibration) and precision [Gauge repeatability and reproducibility (R&R)] can be obtained.

4.3 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 (fluid path surface) shall appear free from particles and extraneous matter.

4.4 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.

4.5 Limits for extractable metals

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

4.6 Size designation

4.6.1 Tubular needle designation

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

a) the designated metric size of the needle tube, may also be expressed in millimetres

   — considering the regional distribution of the products, optionally the needle size expressed in gauge size;

b) the nominal length of the needle tube, expressed in millimetres (Figure 2);

c) optionally, the wall thickness of the needle, expressed as RW (regular wall), TW (thin wall), ETW (extra thin wall), or UTW (ultra-thin wall).

EXAMPLE 0,8 mm × 40 mm TW.

4.6.2 Tapered needle designation

Details necessary for the user to identify the needle, including the designated metric size, shall be provided in accordance with the following expression:

OD (tip)/OD (hub) × L

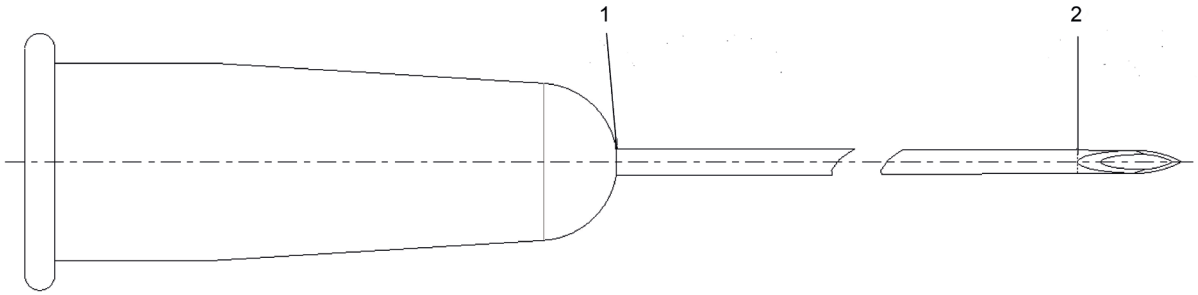
where

OD (tip) is the designated metric size of the needle tube at the first full diameter from the tip (measuring point 2, at the end of the bevel geometry as shown in Figure 1) expressed in millimetres;

OD(hub) is the designated metric size of the needle tube at the hub side, measured at the first full diameter from the top of the hub or from the top of the jointing medium, if used, (measuring point 1 at the end of the hub geometry as shown in Figure 1) expressed in millimetres;

L is the nominal length of the needle tube, expressed in millimetres (Figure 2).

EXAMPLE 0,23 mm/0,25 mm × 6 mm TW.



Key

1 OD. (hub)

2 OD. (tip)

Figure 1 — Tapered needle designation

4.7 Colour coding

The designated metric size of hypodermic tubular needles or the first full diameter from the tip of a tapered needle shall be identified by colour coding in accordance with ISO 6009 applied to the unit packaging and/or part of the needle assembly such as the needle hub or the needle cap.

4.8 Needle hub

4.8.1 Conical fitting

The conical socket of the hypodermic needle hub shall meet the requirements of ISO 80369-1, ISO 594-1 and ISO 594-2.

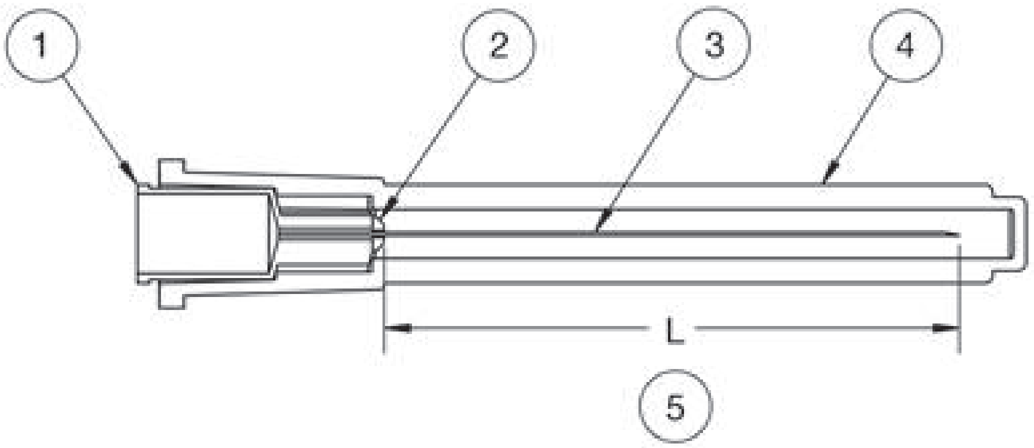
NOTE Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

4.8.2 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.

4.9 Needle cap

If a separate needle cap 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 needle cap

5 length

Figure 2 — Example of a typical hypodermic needle and needle cap for single use

NOTE Figure 2 represents a typical configuration of a hypodermic needle. Specific designs can vary based on the packaging design of the manufacturer.

4.10 Needle tube

4.10.1 General

Needles according to the tubular needle designation shall be in accordance with ISO 9626. For tapered needles, manufacturers shall define how to apply the functional tests specifically stiffness and resistance to breakage on the basis of a specific risk assessment carried out according to ISO 14971.

4.10.2 Tolerances on length

The actual length of the needle tube (see dimension L in Figure 2) 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

4.10.3 Freedom from defects

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the outer surface of the tubing shall be smooth and free from defects.

4.10.4 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 outer or inner surfaces of the needle tube.

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/cm^2 of the lubricated surface area of the needle tube.

4.11 Needle point

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

NOTE The needle point usually has a bevel with a primary bevel angle of 11° ± 2° (as illustrated in Figure 3), but a “short” bevel with other angle, e.g. 17° ± 2°, can be provided.

The designation of needle point dimensions and the nomenclature used to describe the dimensions and features is shown for information in Figure 3. 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 coring 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. Penetration testing can provide an indication of the needle point sharpness and lubrication. An example of a test method for determining the needle penetration performance is given in Annex D.

