DRAFT INTERNATIONAL STANDARD

ISO/DIS 7864

ISO/TC **84**	Secretariat: **DS**
Voting begins on: **2014-12-04**	Voting terminates on: **2015-05-04**

Sterile hypodermic needles for single use — Requirements and test methods

Aiguilles hypodermiques stériles, non réutilisables

ICS: 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 7864:2014(E)

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 7864 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition which has been technically revised.

Introduction

This International Standard covers sterile hypodermic needles intended 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 fittings as specified in ISO/DIS 80369-7[1)] in conjunction with ISO 80369-1 and ISO/DIS 80369-20[2)] .

Devices/connectors intended to mate with hypodermic needles of the standard, but which deviate from ISO 80639-7 shall provide demonstrated evidence of safe functional performance

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

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 'Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters'.

1) Under development

2) Under development

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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*[3)]

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings*[4)]

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

ISO 6009:20XX[5)] , *Hypodermic needles for single use - Colour coding for identification*

ISO 8601:2004, *Data elements and interchange formats - Information interchange -- Representation of dates and times*

ISO 9626:20XX[6)] , *Stainless steel needle tubing for the manufacture of medical devices –Requirements and test methods*

ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

ISO 23908:2011, *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 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements*

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

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

5) Under revision

6) Under revision

ISO/DIS 80369-7: *Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

ISO/FDIS 80369-20: *Small-bore connectors for liquids and gases in healthcare applications -- Part 20: Common test methods*

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:

3.1
gauge
measure of how large a needle is in diameter

NOTE to entry Hypodermic needles are available in a wide variety of outer diameters described by gauge numbers. Smaller gauge numbers indicate larger outer diameters. Inner diameter depends on both gauge and wall thickness.

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

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. The repeatability and reproducibility (Gauge R&R) of the test apparatus shall be no greater than 20 % of the allowed tolerance range for any given measurement.

For destructive test measurements, the Gauge R&R shall be no greater than 30 % of the allowed tolerance range. At a minimum, the Gauge R&R should cover ±2 standard deviations (thereby covering approximately 95 % of the variation).

EXAMPLE A measurement system with a measurement specification limit of ±0,01 ml (range of 0,02 ml) comes out of the Gauge R&R with a Gauge R&R/tolerance range ratio of 20 %, which means that the Gauge R&R (4 standard uncertainties) equals 0,02 ml/5 = 0,004 ml. The uncertainty of the measurement is ±2 standard deviations (Guide to the Expression of Uncertainty in Measurement, GUM), which equals 0,002 ml.

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 x 2,5 magnification, the hub socket 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/1.

4.6 Size designation

For size designation with regards to wall thickness, reference is made to ISO 9626.

4.6.1 Tubular needle designation

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

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

- 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 millimeters (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).

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

EXAMPLE 0,8 X 40 mm TW

4.6.2 Tapered needle designation

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

o.d. (tip)/o.d. (hub) × L

In case of limited space on the packaging, the o.d (tip) designation shall be prioritized for the expression of the size designation.

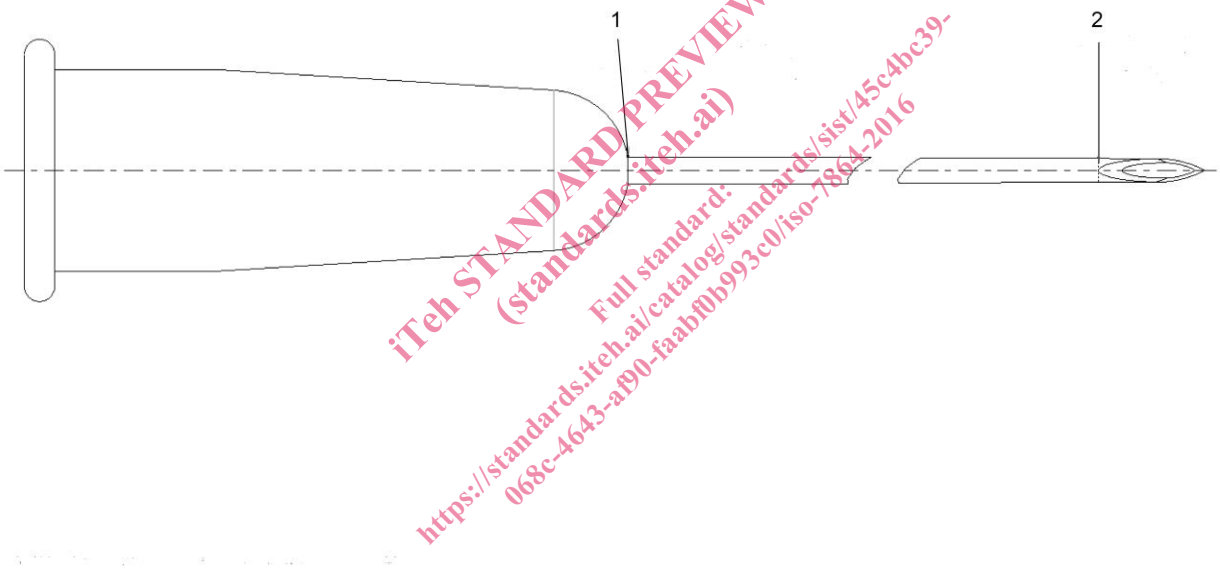
Where:

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

o.d.(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 , expressed in millimeters, as shown in Figure 1;

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

EXAMPLE 0,23/0,25 × 6 mm TW.



Key
1 o.d. (hub)
2 o.d. (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 the tapered needle 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 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

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.