INTERNATIONAL STANDARD

ISO 7864

Fourth edition
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Sterile hypodermic needles for single use — Requirements and test methods

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

Reference number
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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.

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.