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Sterile hypodermic needles for single use — Requirements and test methods

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



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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

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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.

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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.