

# INTERNATIONAL STANDARD

**ISO**  
**7864**

Third edition  
1993-05-15

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## **Sterile hypodermic needles for single use**

*Aiguilles hypodermiques stériles, non réutilisables*



Reference number  
ISO 7864:1993(E)

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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point geometry and fragmentation properties, and the limited number of tests for toxicity given in the 1988 edition has been replaced by an informative annex that lists a significantly greater number of relevant biological tests.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:—<sup>1)</sup>, *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  $\times 2,5$  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.