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Second edition  
2017-05

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# **Sterile hypodermic syringes for single use —**

## **Part 1: Syringes for manual use**

*Seringues hypodermiques stériles, non réutilisables —  
Partie 1: Seringues pour utilisation manuelle*



Reference number  
ISO 7886-1:2017(E)

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## Contents

	Page
<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Nomenclature</b> .....	<b>3</b>
<b>5 General requirements</b> .....	<b>5</b>
<b>6 Extraneous matter</b> .....	<b>5</b>
6.1 General.....	5
6.2 Limits for acidity or alkalinity.....	5
6.3 Limits for extractable metals.....	5
<b>7 Lubricant</b> .....	<b>6</b>
<b>8 Tolerance on graduated capacity</b> .....	<b>6</b>
<b>9 Graduated scale</b> .....	<b>7</b>
9.1 Scale.....	7
9.2 Numbering of scales.....	8
9.3 Overall length of scale to nominal capacity line.....	8
9.4 Position of scale.....	9
<b>10 Barrel</b> .....	<b>9</b>
10.1 Dimensions.....	9
10.2 Barrel flanges.....	9
<b>11 Plunger stopper/plunger assembly</b> .....	<b>9</b>
11.1 Design.....	9
<b>12 Nozzle</b> .....	<b>10</b>
12.1 Conical fitting.....	10
12.2 Position of nozzle on end of barrel.....	10
12.3 Nozzle lumen.....	10
<b>13 Performance</b> .....	<b>10</b>
13.1 Dead space.....	10
13.2 Freedom from air and liquid leakage past plunger stopper.....	10
13.3 Force to operate the piston.....	10
13.4 Fit of plunger stopper/plunger in barrel.....	10
<b>14 Packaging</b> .....	<b>11</b>
14.1 Unit packaging and self-contained syringe units.....	11
14.1.1 Unit packaging.....	11
14.1.2 Self-contained syringe units.....	11
14.2 Multiple unit pack.....	11
14.3 User packaging.....	11
<b>15 Information supplied by the manufacturer</b> .....	<b>12</b>
15.1 General.....	12
15.2 Syringes.....	12
15.2.1 General.....	12
15.2.2 Additional marking for self-contained syringe units.....	12
15.3 Unit packaging.....	12
15.4 Multiple unit packs.....	13
15.4.1 General.....	13
15.4.2 Multiple unit packs with self-contained syringes.....	13
15.5 User packaging.....	13

This is a preview of "ISO 7886-1:2017". [Click here to purchase the full version from the ANSI store.](#)

15.6	Storage container.....	14
15.7	Transport wrapping.....	14
<b>Annex A (normative) Method for preparation of extracts.....</b>		<b>15</b>
<b>Annex B (normative) Test method for air leakage past syringe plunger stopper during aspiration, and for separation of plunger stopper and plunger.....</b>		<b>16</b>
<b>Annex C (normative) Method for determination of dead space.....</b>		<b>18</b>
<b>Annex D (normative) Test method for liquid leakage at syringe plunger stopper under compression.....</b>		<b>19</b>
<b>Annex E (informative) Test method for the determination of forces required to operate the piston.....</b>		<b>21</b>
<b>Annex F (informative) Test method for the quantity of silicone.....</b>		<b>25</b>
<b>Bibliography.....</b>		<b>28</b>

This is a preview of "ISO 7886-1:2017". [Click here to purchase the full version from the ANSI store.](#)

## 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](http://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](http://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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document 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 (ISO 7886-1:1993), which has been technically revised. It also incorporates the Technical corrigendum ISO 7886-1:1993/Cor.1:1995.

The main changes to the previous edition are the following:

- a) clarified the Scope, e.g. excluding single-use syringes made of glass;
- b) added new Normative references;
- c) added new terms and definitions;
- d) clarified the drawing to illustrate the component of the syringe;
- e) included general requirements;
- f) revised test methods for syringes;
- g) revised the labelling requirement;
- h) clarified the type of lubricant for the different types of syringes;
- i) replaced Annex E (informative): Examples of test methods for incompatibility between syringes and injection fluids with [Annex E](#) (informative): Test method for the determination of forces required to operate the piston;
- j) added [Annex F](#) (informative): Test method for the quantity of silicone;
- k) informative annex on materials has been deleted.

A list of all parts in the ISO 7886 series can be found on the ISO website.

## Introduction

The ISO 7886 series covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as not to limit innovation and methods of packaging. Its appearance and layout are consistent with other related standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in this document. Several limits for requirements which are historic based but confirmed in practice for many years have been kept.

Materials to be used for the construction and lubrication of sterile syringes for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers. The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling on unit packaging. It is not practicable to specify a universally acceptable test method for incompatibility, as the only conclusive test is that an individual specific injection fluid is compatible with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. If an incompatibility is identified, the injection fluid should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers of injectable preparations.

Syringes should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

The sampling plans for inspection selected for the ISO 7886 series are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems requirements that appear in standards on quality systems, for example the ISO 9000 series and ISO 13485.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of syringes.

Guidance on transition periods for implementing the requirements of ISO 7886 (all parts) is given in ISO/TR 19244.