
Sterile hypodermic syringes for single use —

Part 4: Syringes with re-use prevention feature

Seringues hypodermiques stériles, non réutilisables —

Partie 4: Seringues avec dispositif empêchant la réutilisation



This document is a preview generated by EMS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Types of syringe	2
4.1 General	2
4.2 Types of re-use prevention feature	2
4.3 Types of intended use/application	2
5 Extraneous matter	2
5.1 General	2
5.2 Limits for acidity or alkalinity	2
5.3 Limits for extractable metals	2
6 Lubricant	3
7 Tolerance on graduated capacity	3
8 Graduated scale	3
8.1 Scale	3
8.2 Numbering of scale	3
8.3 Position of scale	3
8.4 Overall length of scale to nominal capacity line	3
9 Barrel	3
9.1 Dimensions	3
9.2 Barrel flanges	3
10 Plunger stopper/plunger assembly	3
10.1 Design	3
10.2 Fit of plunger stopper/plunger in the barrel	4
10.3 Fiducial line	4
11 Syringe nozzle/needle	4
11.1 Syringe with integrated needle	4
11.2 Syringe with Luer nozzle	4
12 Performance	4
12.1 Dead space	4
12.2 Freedom from air and liquid leakage	4
12.3 Re-use prevention feature	5
12.4 Performance after shipping	5
13 Packaging	5
13.1 Unit packaging and self-contained syringe units	5
13.2 Multiple unit pack	5
13.3 User packaging	5
14 Information supplied by the manufacturer	5
14.1 General	5
14.2 Syringes	5
14.2.1 General	5
14.2.2 Unit packaging	5
14.3 Multiple unit packs	6
14.3.1 General	6
14.3.2 Multiple unit packs with self-contained syringes	6
14.4 User packaging	6

14.4.1	General	6
14.4.2	Storage container	6
14.5	Transport wrapping	6
Annex A (normative) Method for preparation of extracts		7
Annex B (normative) Test method for testing re-use prevention feature		8
Bibliography		10

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 of 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 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 7886-4:2006), which has been technically revised. The main changes compared to the previous edition are as follows:

- terminology in Introduction is clarified;
- general reference update (Normative references, Bibliography and main body of the text);
- definitions for "active activation" and "auto-disable feature" added;
- test of syringes: Harmonized definitions with ISO 7886-3 and clarified text;
- [Figure 1](#) is removed and substituted with a reference to the figure in ISO 7886-1;
- barrel dimension – the additional 20 % capacity is removed;
- dimensions in design section are clarified;
- alignment with ISO 7886-1 and ISO 7886-3;
- subclause 15.5, Guidance on material, has been removed;
- Figure 3 (safety box) is removed;
- Annex C is deleted.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The preparation of this document was recognized as a high priority requirement to prevent intentional (misuse) or accidental reuse of syringes. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [5] in the Bibliography.

The World Health Organisation (WHO) had produced a specification for syringes that are rendered inactive after use [commonly referred to as “auto-disable” (AD) syringes] for both fixed dose immunization and syringes with re-use prevention features for general/curative purposes and the reconstitution of vaccines. For the purpose of this document, auto disabled is used for the feature of type 1 re-use prevention which operates automatically during or upon completion of the intended single use. Both the WHO and ISO agreed that additional parts of ISO 7886 would be required to cover syringes with re-use prevention features, while leaving in place ISO 7886-1 and ISO 7886-2 without modification, as a large number of devices in common use would not be intended to comply with the re-use prevention properties suggested.

This document is intended to cover syringes that are rendered inoperable, either during or upon completion or after delivery of the intended dose. These syringes are not covered by ISO 7886-1 and ISO 7886-3. ISO 7886-2 covers syringes used with power-driven pumps. Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention is to be considered for each specific intended use.

It is recognized that syringes designed to reduce the risk of needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Sterile hypodermic syringes for single use —

Part 4:

Syringes with re-use prevention feature

1 Scope

This document specifies requirements for sterile single-use hypodermic syringes made of plastic and rubber materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This document is not applicable to syringes made of glass [specified in ISO 595 (withdrawn)], auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this document.

NOTE Syringes designed to reduce the risk of needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:2016, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1, ISO 8537 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>