INTERNATIONAL STANDARD

ISO 7886-4

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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

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 7886-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

— *Part 1: Syringes for manual use*

— *Part 2: Syringes for use with power-driven syringe pumps*

— *Part 3: Auto-disable syringes for fixed-dose immunization*

— *Part 4: Syringes with re-use prevention feature*

Introduction

The preparation of this part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of syringes in the developing and transitional countries. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [1] in the Bibliography.

The World Health Organisation had produced a specification for syringes that are rendered inactive after use (commonly referred to as “auto-disable” syringes) for fixed dose immunization and syringes with re-use prevention features for general purpose. Both the WHO and ISO agreed that additional parts of ISO 7886 would be required to cover syringes with re-use prevention features, whilst 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 part of ISO 7886 is intended to cover syringes that are rendered inoperable 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 needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

Sterile hypodermic syringes for single use —

Part 4:
Syringes with re-use prevention feature

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics 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 part of ISO 7886 is not applicable to syringes made of glass (specified in ISO 595), 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 part of ISO 7886.

NOTE Syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

2 Normative references

The following referenced documents are indispensable for the application 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 780, *Packaging — Pictorial marking for handling of goods*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:1991, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

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*