Second edition
2020-05

Sterile hypodermic syringes for single use —

Part 3: Auto-disabled syringes for fixed-dose immunization

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe

Reference number
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Contents

Foreword

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7886-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— update of the references, mainly ISO 7886-1:2017.

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

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts: ISO 7886-1 retaining essentially the scope of ISO 7886:1984 and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this document was recognized as a high priority to prevent the reuse of fixed dose immunization syringes. Reuse of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens.

The World Health Organization (WHO) had produced a specification for syringes that are rendered inactive after one use (commonly referred to as “auto-disabled” syringes). It was agreed that an additional part of the ISO 7886 series would be needed to cover “auto-disabled” syringes, 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 conform with the auto-disable properties suggested.

It has been discussed to limit the syringe types to only comprise the type having an auto-disable syringe feature that is automatically activated and remains effective from the time that the injection is commenced. An assessment of potential hazards based only on hypothetical use indicates that the type having an auto-disable syringe feature that is automatically activated and remains effective from the time of the injection being initiated is potentially safer than the other types. However, no consensus could be reached on either deleting types or retaining them, as no reliable risk data from field use exists at present. It was therefore agreed to retain all types and restrict this revision to alignment with ISO 7886-1:2017 and initiate a new revision if new field studies or incident reports indicate a need for a revision.

It is recognized that syringes designed to reduce the risk of needle stick injuries can also conform with this document.

In some countries national regulations might take precedence over the requirements in this document.

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