Irish Standard
I.S. EN ISO 7886-3:2009

Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886 -3:2005)

I.S. EN ISO 7886-3:2009

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EUROPEAN STANDARD

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EN ISO 7886-3

September 2009

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Supersedes EN ISO 7886-3:2005

English Version

Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)

Seringues hypodermiques stériles, non réutilisables - Partie 3: Seringues autobloquantes pour vaccination à dose fixe (ISO 7886-3:2005)

Sterile Einmalspritzen für medizinische Zwecke - Teil 3: Selbstblockierende Spritzen für die Injektion mit fixer Impfstoffdosis (ISO 7886-3:2005)

This European Standard was approved by CEN on 24 August 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Ref. No. EN ISO 7886-3:2009: E

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Foreword

The text of ISO 7886-3:2005 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7886-3:2009.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7886-3:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7886-3:2005 has been approved by CEN as a EN ISO 7886-3:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1, 7.1, 7.2, 7.5	E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed.
6	1, 7.1, 7.2, 7.5	E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed.
7	1, 7.1, 7.2, 7.5	E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed.
8	1, 7.1, 7.2, 7.5	E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed.
9	10.1, 10.3	
10	1, 10.1, 10.2, 10.3	
11.1	1, 10.1, 10.2	
11.2	10.2	
12.1	1, 2, 3, 10.2, 12.8.2	
12.2	1, 2, 3, 12.8.1, 12.8.2	
12.3	10.2	
13.1	1, 2	

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	
13.2	1, 2, 9.1	
14.1	1, 2, 10.1, 10.3	
14.2	1, 2, 7.5, 7.6	
14.3	1, 2, 3, 12.8.2, 8.1	
14.4	5	
15.1	3, 7.2, 8.3, 8,7	
15.2	7.2, 8.3, 8,7	
16	13.1, 13.2, 13.3, 13.4, 13.5, 13.6	Except 13.3 (f) (second phrase regarding indication of single use consistent across community), except 13.3 (a) (regarding representative in the Community), except 13.6 (h) – 2nd phrase (information on known characteristics and technical factors known to manufacturer that could pose a risk if reused) and 13.6 (q) (regarding date of issue or latest revision of instructions for use)
NOTE	6 a	Requirement on clinical evaluation not covered by this standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 7886-3:2009

INTERNATIONAL STANDARD

ISO 7886-3

First edition
2005-03-01

Sterile hypodermic syringes for single use —

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

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe

Reference number
ISO 7886-3:2005(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.

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 7886-3 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 reuse prevention feature*

For the purposes of this part of ISO 7886, the CEN annex regarding fulfilment of European Council Directives has been removed.

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 third part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of fixed dose immunization 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.

The World Health Organization had produced a specification for syringes that are rendered inactive after use (commonly referred to as “auto-disable” syringes). Both the WHO and ISO agreed that an additional part of ISO 7886 would be required to cover “auto-disable” syringes, whilst leaving in place ISO 7886 Parts 1 and 2 without modification, as a large number of devices in common use would not be intended to comply with the auto-disable properties suggested.

This part of ISO 7886 is intended to cover “fixed dose” immunization syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by Parts 1 and 2 of ISO 7886.

It is recognized that syringes designed to reduce the risk of needlestick injuries, in addition to preventing sharps injuries, may also comply with this part of ISO 7886 with regard to their auto-disable properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.