This is a free page sample. Access the full version online.

NSAI Standards

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)

© NSAI 2009 No copying without NSAI permission except as permitted by copyright law.

This is a free page sample. Access the full version online.

# I.S. EN ISO 7886-3:2009

*Incorporating amendments/corrigenda issued since publication:*

| *This document replaces:* | *This document is based on:* | *Published:* |
|---|---|---|
| EN ISO 7886-3:2005 | EN ISO 7886-3:2009<br>EN ISO 7886-3:2005 | 23 September, 2009<br>25 May, 2005 |

| | |
|---|---|
| This document was published under the authority of the NSAI and comes into effect on:<br>14 October, 2009 | ICS number:<br>11.040.25 |

**NSAI**
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

**Sales:**
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.



EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 7886-3

September 2009

ICS 11.040.25

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.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

© 2009 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

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

This is a free page sample. Access the full version online.



# Contents

Page

**Foreword** ..... 3

**Annex ZA** (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices** ..... 4

This is a free page sample. Access the full version online.



# 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.

This is a free page sample. Access the full version online.



# 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 | |

This is a free page sample. Access the full version online.



**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),<br>except 13.3 (a) (regarding representative in the Community),<br>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.

This is a free page sample. Access the full version online.



*This page is intentionally left BLANK.*

This is a free page sample. Access the full version online.

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)

© ISO 2005

This is a free page sample. Access the full version online.



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2005

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

This is a free page sample. Access the full version online.



# Contents

Page

**Foreword** ..... iv
**Introduction** ..... v
**1 Scope** ..... 1
**2 Normative references** ..... 1
**3 Terms and definitions** ..... 2
**4 Nomenclature** ..... 2
**5 Cleanliness** ..... 3
**6 Limits for acidity or alkalinity** ..... 3
**7 Limits for extractable metals** ..... 3
**8 Lubricant** ..... 3
**9 Tolerance on nominal capacity** ..... 3
**10 Graduated scale** ..... 3
**11 Barrel** ..... 4
**12 Piston/plunger assembly** ..... 4
**13 Needle** ..... 4
**14 Performance** ..... 5
**15 Packaging** ..... 6
**16 Labelling** ..... 6
**Annex A** (normative) **Method for preparation of extracts** ..... 9
**Annex B** (informative) **Test method for forces required to operate plunger** ..... 10
**Annex C** (normative) **Test method for testing auto-disable feature** ..... 12
**Bibliography** ..... 13

© ISO 2005 – All rights reserved 

This is a free page sample. Access the full version online.



# 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.


© ISO 2005 – All rights reserved

This is a free page sample. Access the full version online.



# 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.

V© ISO 2005 – All rights reserved

SAI GLOBAL

This is a free preview.  Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation