

Sterile hypodermic syringes for single use

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

ICS 11.040.25

National foreword

This British Standard is the UK implementation of EN ISO 7886-3:2009. It is identical to ISO 7886-3:2005. It supersedes BS EN ISO 7886-3:2005 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2009.
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ISBN 978 0 580 67785 4

Amendments/corrigenda issued since publication

Date	Comments

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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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) – 2 nd 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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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.