SLOVENSKI STANDARD
SIST EN ISO 7886-4:2007

01-oktober-2007

Sterilne podkoģne injekcijske brizge za enkratno uporabo - 4. del: Injekcije, katerih znaļ ilnosti prepreļ ujejo ponovno uporabo (ISO 7886-4:2006)

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)

Sterile Einmalspritzen für medizinische Zwecke - Teil 4: Spritzen mit Vorrichtung zur Verhinderung der Wiederverwendung (ISO 7886-4:2006)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empechant la réutilisation (ISO 7886-4:2006)

Ta slovenski standard je istoveten z: **EN ISO 7886-4:2006**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 7886-4:2007 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7886-4

October 2006

ICS 11.040.25

English Version

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empêchant la réutilisation (ISO 7886-4:2006)

Sterile Einmalspritzen für medizinische Zwecke - Teil 4: Spritzen mit Vorrichtung zur Verhinderung der Wiederverwendung (ISO 7886-4:2006)

This European Standard was approved by CEN on 19 August 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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

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Ref. No. EN ISO 7886-4:2006: E

Foreword

This document (EN ISO 7886-4:2006) has been prepared by Technical Committee ISO/TC 84 "Medical devices for injections" in collaboration with CMC.

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 April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

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(s).

For relationship with EU Directive(s), 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, 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.

Endorsement notice

The text of ISO 7886-4:2006 has been approved by CEN as EN ISO 7886-4:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC 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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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 Medical devices

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
6	7.2 – 7.5	
7	7.2 – 7.5	
8	7.2 – 7.5	
9	7.2 – 7.5	
10	10.1	
11	10.1	
11.1	10.1	
11.2	10.1	
11.3	10.1	
12	9.2	
12.1	9.2	
12.2	9.2	
13.1	1 – 9.2	
13.2	1 – 9.2	
13.3	10.1	
14.1	2	
14.2	9.1	
15.1	No direct reference/link to MDD 93/42/EEC.	Essential Requirements 7.3 and 10.1 of the Directive are the closest links to this design characteristic of the syringe.
15.2	7.5 – 10.1	
15.3	1 – 2 – 8.1	
15.4	5	
15.5	7.1	

Table ZA.1 (*continued*)

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
16.1	7.2, 8.3	
16.2	7.2, 8.3	
17	13.1	
17.2.1 a)	13.2 – 13.3 f	
17.2.1 b)	13.2	
17.2.1 c)	13.3 a	
17.2.1 d)	13.2 – 13.3 c	
17.2.1 e)	13.2 – 13.3 d	
17.2.1 f)	13.2 – 13.3 e	
17.2.1 g)	13.3 b	
17.2.2 a)	13.2 – 13.3 f	
17.2.2 b)	13.2	
17.2.2 c)	13.3 a)	
17.2.2 d)	13.2 – 13.3 c	
17.2.2 e)	13.2 – 13.3 d	
17.2.2 f)	13.2 – 13.3 e	
17.2.2 g)	13.3 b	
17.3 a)	13.2 – 13.3 f	
17.3 b)	13.2	
17.3 c)	13.3 a	
17.3 d)	13.2 – 13.3 c	
17.3 e)	13.2 – 13.3 d	
17.3 f)	13.2 – 13.3 e	
17.3 g)	13.3 b	
17.3 h)	13.3 k	
17.3 i)	13.3 k	
17.3 j)	13.3 i	
17.3 k)	13.6	
17.3 l)	13.3 b	
17.4 a)	13.3 b	
17.4 b)	13.2	
17.4 c)	13.2 – 13.3 d	
17.4 d)	13.2 – 13.3 e	
17.4 e)	13.2 – 13.3 c	
17.4 f)	13.3 a	
17.4 g)	13.3 i	
17.4 h)	13.3 b	

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

INTERNATIONAL STANDARD

ISO 7886-4

First edition
2006-10-01

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

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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.