SLOVENSKI STANDARD
SIST EN ISO 7886-2:2000

01-januar-2000

Sterilne podkoģne injekcijske brizge za enkratno uporabo - 2. del: Injekcijske brizge za injiciranje z injekcijskimi ļ rpalkami (ISO 7886-2:1996)

Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:1996)

Sterile Einmalspritzen für medizinische Zwecke - Teil 2: Spritzen zur Verwendung mit Spritzenpumpen (ISO 7886-2:1996)

Seringues hypodermiques stériles, non réutilisables - Partie 2: Seringues pour pousse-seringues mus par un moteur (ISO 7886-2:1996)

Ta slovenski standard je istoveten z: **EN ISO 7886-2:1997**

ICS:

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

SIST EN ISO 7886-2:2000 **en**

EUROPEAN STANDARD

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English version

Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:1996)

Seringues hypodermiques stériles, non réutilisables - Partie 2: Seringues pour pousse-seringues mûs par un moteur (ISO 7886-2:1996)

Sterile Einmalspritzen für medizinische Zwecke - Teil 2: Spritzen zur Verwendung mit Spritzenpumpen (ISO 7886-2:1996)

This European Standard was approved by CEN on 1997-08-23. 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.

The European Standards exist 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.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 84 "Medical devices for injections" of the International Organization for Standardization (ISO) has been taken over as an European Standard by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

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 1998, and conflicting national standards shall be withdrawn at the latest by March 1998.

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

Endorsement notice

The text of the International Standard ISO 7886-2:1996 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 594-1	1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1 : General requirements	EN 20594-1	1993
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995
ISO 7864	1993	Sterile hypodermic needles for single use	EN ISO 7864	1995
ISO 7886-1	1993	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use	EN ISO 7886-1	1997
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times	EN 28601	1992

INTERNATIONAL STANDARD

ISO 7886-2

First edition
1996-05-15

Sterile hypodermic syringes for single use —

Part 2:
Syringes for use with power-driven syringe pumps

Seringues hypodermiques stériles, non réutilisables —

Partie 2: Seringues pour pousse-seringues mûs par un moteur

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Contents

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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.

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.

International Standard ISO 7886-2 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, 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*

Annexes A, B and C form an integral part of this part of ISO 7886. Annexes D and E are for information only.

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.

Introduction

1 General

In the preparation of this part of ISO 7886, it was recognized at an early stage that the absolute criterion of performance is achieved by the combination of the power-driven syringe pump and the syringe working as a complete system. The dependence of one element of the system on the performance of the other is a key factor. It is essential for the manufacturer of one of these components to liaise with the manufacturer of the other when considering changes in design, in order to ensure satisfactory operation of the system. In particular, when requested by a pump manufacturer, a syringe manufacturer should give information on tolerances and relationships between the syringe dimensions specified in this part of ISO 7886 and on performance characteristics, such as force to move the plunger, and the variations which might be expected.

2 Design criteria

The use of syringes which were initially designed and used as manually-operated devices in syringe pumps now makes it desirable to achieve much tighter tolerances on syringe dimensions than normally required for manual use.

It is understood that the degree of investment worldwide by all syringe manufacturers in moulding and manufacturing equipment is such that a change such as modifying diameters of push-buttons or the barrel inside diameter is largely out of reach of the syringe industry.

Typically the hard height of a syringe has never been regarded as a particularly critical dimension. Its tolerances are ordinarily relatively loose. The hard-height dimension is a function of not only the total length of plunger rod and the barrel, but also the thickness of the piston and finger grips. The piston thickness, by virtue of its relatively unsophisticated manufacturing process, can vary considerably. Because all these components are manufactured in multicavity moulds from many moulds around the world, the cumulative extreme tolerance buildup from cavity to cavity and mould to mould and location to location is such that these previously noncritical dimensions cannot be instantly tightened.

3 Syringe identification

It is important that when a syringe is fitted to a syringe pump, the pump is correctly programmed to perform satisfactorily with the particular syringe installed.

In view of the consequences of incorrect syringe identification by the pump, the need for an automatic system is recognized. Methods already in

use, such as mechanical sensing of the syringe outside diameter, are not deemed feasible in the long term. This is due to overlapping ranges of diameter of syringes produced by different manufacturers, and the lack of relationship between the outside and inside diameters of a syringe. It is also recognized that standardization of syringe barrel diameters across the industry is not a realistic option.

A means by which the pump could automatically identify the syringe model and use this to programme such information as barrel inside diameter, plunger force and occlusion alarm settings is seen as the next stage of this part of ISO 7886. A possible method of recognition is to identify the syringe and nominal capacity by means of a marking code on the barrel, printed at the same time as the syringe scale, and to use this to programme the pump automatically. It is recommended that development of such a system be worked on as soon as possible.