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Steriilsed nahaalusteks süsteteks ettenähtud ühekordselt kasutatavad süstlad. Osa 2: Mootoriga käitatavates süstepumpades (perfuusorites) kasutatavad süstlad

Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 7886-2:1999 sisaldab Euroopa standardi EN ISO 7886-2:1997 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 7886-2:1999 consists of the English text of the European standard EN ISO 7886-2:1997. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Standardi käesolev osa esitab nõuded steriilsetele ühekordselt kasutatavatele nahaalusteks süsteteks ettenähtud süstaldele, mille nominaalmaht on 5 ml ja üle selle ning mis on valmistatud plastist ja ette nähtud kasutamiseks mootoriga käitatavates süstepumpades (perfuusorites). Standardi käesolev osa ei kehti insuliini süstimiseks ettenähtud süstalde, klaasist valmistatud ühekordselt kasutatavate süstalde, tootja poolt süstitava preparaadiga täidetud süstalde ning selliste süstalde kohta, mis moodustavad juurdekuuluva süstitava preparaadiga komplekti ja täidetakse farmatseudi poolt.	**Scope:**

ICS 11.040.20

Võtmesõnad: jõudlus, meditsiiniaparatuur, mõõtmed, pakendamine, pärast kasutamist hävitatavad vahendid, sildiga märgistamine, steriilne varustus, süstlad, tehnilised andmed, testimine

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Eesti Standardikeskusele kuulub standardite reprodutseerimis- ja levitamisõigus

EUROPEAN STANDARD
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EN ISO 7886-2

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Descriptors: Syringes, hypodermic syringes, medical equipment.

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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.

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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.

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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

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Foreword

International Standard

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

which was prepared by ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by March 1998 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

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

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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Contents

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.

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1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes of nominal capacity 5 ml and above, made of plastics materials and intended for use with power-driven syringe pumps.

This part of ISO 7886 does not apply to syringes for use with insulin (specified in ISO 8537), single-use syringes made of glass (specified in ISO 595), syringes prefilled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist. It does not address compatibility with injection fluids.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7886. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7886 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1990, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 7864:1993, *Sterile hypodermic needles for single use.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

IEC 601-2-24:—[1)], *Medical electrical equipment — Part 2: Particular requirements for safety of infusion pumps and controllers.*

3 Definitions

For the purposes of this part of ISO 7886, the definitions given in ISO 7886-1 apply.

4 Nomenclature

Clause 4 of ISO 7886-1:1993 shall apply.

5 Cleanliness

Clause 5 of ISO 7886-1:1993 shall apply.

6 Limits for acidity or alkalinity

Clause 6 of ISO 7886-1:1993 shall apply.

1) To be published.

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