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

Reference number
ISO 7886-2:1996(E)

Contents

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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.

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Sterile hypodermic syringes for single use —

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

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.