ICS 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA August 2020

STN	**Sterilné injekčné striekačky na jednorazové použitie Časť 2: Striekačky používané s dávkovačmi (ISO 7886-2: 2020)**	**STN EN ISO 7886-2 85 6170**

Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:2020)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/20

Obsahuje: EN ISO 7886-2:2020, ISO 7886-2:2020

Oznámením tejto normy sa ruší
STN EN ISO 7886-2 (85 6170) z novembra 2000

131288

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7886-2

May 2020

ICS 11.040.25 Supersedes EN ISO 7886-2:1997

English Version

Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:2020)

Seringues hypodermiques stériles, non réutilisables - Partie 2: Seringues pour pousse-seringues électriques (ISO 7886-2:2020)

Sterile Einmalspritzen für medizinische Zwecke - Teil 2: Spritzen zur Verwendung mit Spritzenpumpen (ISO 7886-2:2020)

This European Standard was approved by CEN on 27 April 2020.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 7886-2:2020) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7886-2:1997.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7886-2:2020 has been approved by CEN as EN ISO 7886-2:2020 without any modification.

INTERNATIONAL STANDARD

ISO 7886-2

Second edition
2020-04

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 électriques

Reference number
ISO 7886-2:2020(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 7886-2:1996), which has been technically revised. The main changes compared to the previous edition are as follows:

— Syringe sizes 1 ml to 5 ml were added to the scope of this document.

— Overall flow rate requirement was removed from Clause 14 as it is predominantly affected by the barrel inner diameter (ID), which is addressed in Clause 11.

— Pump test speeds were adjusted for each syringe size to better reflect the range of speeds used in general clinical settings.

A list of all parts in the ISO 7886 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

In the preparation of this document, 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, a syringe manufacturer should give information on tolerances and relationships between the syringe dimensions specified in this document and on performance characteristics such as the force to move the plunger, and the variation which might be expected.

The selection of test speeds for flow rate accuracy recognized that low speeds are worse-case and result in large variation; however, selecting speeds of less than 1 ml/h was considered inappropriate due to limitations of the gravimetric test method error (due to factors such as balance stabilization and difficulty in measuring micro amounts of fluid using balances designed for static measurements).

It is recognized that start-up time and travel through parking position may impact pump forces and should be considered for exclusion, if necessary.

The syringe driver and measurement equipment characteristics might influence test method error; therefore, it is recommended to include the appropriate level of accuracy and precision of equipment and to perform test method validations.

0.2 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 molding and manufacturing equipment is such that a change such as modifying diameters of push-buttons or the barrel inner diameter (ID) 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 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 barrel flanges. The piston thickness, by virtue of its relatively unsophisticated manufacturing process, can vary considerably. Because all these components are manufactured in multi-cavity molds from many molds around the world, the cumulative extreme tolerance buildup from cavity to cavity and mold to mold and location to location is such that these previously noncritical dimensions cannot be instantly tightened.

0.3 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 outer diameter, are not deemed feasible in the long term to reduce errors in syringe identification. This is due to overlapping ranges of diameter of syringes produced by different manufacturers. It is also recognized that standardization of syringe barrel diameters (IDs) across the industry is not a realistic option.

A means by which the pump could automatically identify the syringe model and use this to program such information as barrel inner diameter (ID), plunger force and occlusion alarm settings is seen as the next stage of this standard. 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 program the pump automatically. It is recommended that development of such a system be worked on as soon as possible.

0.4 Infusion speeds and syringe size selection

The flow rates described in this document are for syringe tests and are not recommendations for clinical practice.

In general, as flow rate accuracy is dependent on linear travel of the plunger/pump driver, smaller size syringes tend to have a higher resolution and they also tend to have a higher flow rate accuracy at slower speeds.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244[1].

INTERNATIONAL STANDARD **ISO 7886-2:2020(E)**

Sterile hypodermic syringes for single use —

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

1 Scope

This document specifies requirements for sterile single-use hypodermic syringes of nominal capacity 1 ml and above, made of plastic materials and intended for use with power-driven syringe pumps.

This document does not apply to syringes with auto-disable syringe features (ISO 7886-3[2]), syringes for use with insulin (ISO 8537[3]), single-use syringes made of glass, 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*