



SLOVENSKI STANDARD SIST EN ISO 7886-3:2020

01-julij-2020

Nadomešča:
SIST EN ISO 7886-3:2010

Sterilne podkožne injekcijske brizge za enkratno uporabo - 3. del: Brizge za točno določen odmerek imunizacije s sistemom za samouničenje (ISO 7886-3:2020)

Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization (ISO 7886-3:2020)

Sterile Einmalspritzen für medizinische Zwecke - Teil 3: Selbstblockierende Spritzen für die Injektion mit fixer Impfstoffdosis (ISO 7886-3:2020)

Seringues hypodermiques stériles, non réutilisables - Partie 3: Seringues autobloquantes pour vaccination à dose fixe (ISO 7886-3:2020)

Ta slovenski standard je istoveten z: EN ISO 7886-3:2020

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
-----------	-------------------------------------	---------------------------------

SIST EN ISO 7886-3:2020

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 7886-3:2020](#)

<https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>

EUROPEAN STANDARD

EN ISO 7886-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2020

ICS 11.040.25

Supersedes EN ISO 7886-3:2009

English Version

Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization (ISO 7886-3:2020)

Seringues hypodermiques stériles, non réutilisables -
Partie 3: Seringues autobloquantes pour vaccination à
dose fixe (ISO 7886-3:2020)

Sterile Einmalspritzen für medizinische Zwecke - Teil
3: Selbstblockierende Spritzen für die Injektion mit
fixer Impfstoffdosis (ISO 7886-3:2020)

This European Standard was approved by CEN on 24 April 2020.

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 CEN-CENELEC Management Centre or to any CEN member.

iTeh STANDARD PREVIEW

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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 7886-3:2020

<https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>

European foreword

This document (EN ISO 7886-3:2020) 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 7886-3:2009.

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.

iTeh STANDARD PREVIEW
Endorsement notice
(standards.iteh.ai)

The text of ISO 7886-3:2020 has been approved by CEN as EN ISO 7886-3:2020 without any modification.

[SIST EN ISO 7886-3:2020
https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020](https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 7886-3:2020](#)

<https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>

INTERNATIONAL
STANDARD

ISO
7886-3

Second edition
2020-05

**Sterile hypodermic syringes for
single use —**

**Part 3:
Auto-disabled syringes for fixed-dose
immunization**

iTeh STANDARD PREVIEW
Seringues hypodermiques stériles, non réutilisables —
(Partie 3: Seringues autobloquantes pour vaccination à dose fixe
(standards.iteh.ai))

[SIST EN ISO 7886-3:2020](https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020)

<https://standards.iteh.ai/catalog/standards/sist/fbb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>



Reference number
ISO 7886-3:2020(E)

© ISO 2020

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 7886-3:2020

<https://standards.iteh.ai/catalog/standards/sist/fb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword.....	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Nomenclature	2
5 General requirements	3
6 Extraneous matter	4
6.1 General.....	4
6.2 Limits for acidity or alkalinity.....	4
6.3 Limits for extractable metals.....	4
7 Lubricant	4
8 Tolerance on nominal capacity	4
9 Graduated scale	5
9.1 Scale.....	5
9.2 Position of scale.....	5
10 Barrel	5
10.1 Dimensions.....	5
10.2 Barrel flanges.....	5
11 Plunger stopper/plunger assembly	5
11.1 Design.....	5
11.2 Fit of the plunger stopper/plunger in the barrel.....	6
11.3 Fiducial line.....	6
12 Needle	6
12.1 General.....	6
12.2 Integrated needle.....	6
12.3 Non-integrated needle.....	6
12.4 Sharps protection features.....	6
13 Performance	7
13.1 General.....	7
13.2 Dead space.....	7
13.3 Freedom from air and liquid leakage.....	7
13.4 Auto-disable syringe feature.....	7
13.5 Performance after shipping.....	7
14 Packaging	8
14.1 Unit packaging providing sterile barrier.....	8
14.2 Multiple unit pack.....	8
14.3 User packaging.....	8
15 Information supplied by the manufacturer	8
15.1 General.....	8
15.2 Syringes.....	8
15.3 Unit packaging providing sterile barrier.....	8
15.4 User packaging.....	9
15.5 Storage containers.....	9
15.6 Transport wrapping.....	10
Annex A (normative) Method for preparation of extracts	11
Annex B (informative) Test method for forces required to operate piston	12

ISO 7886-3:2020(E)

Annex C (normative) Test method for testing auto-disable syringe feature..... 14
Bibliography 15

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 7886-3:2020

<https://standards.iteh.ai/catalog/standards/sist/fb1bd81-6f8f-45f4-93c9-4e2568b0e638/sist-en-iso-7886-3-2020>

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7886-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— update of the references, mainly ISO 7886-1:2017.

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.