



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 7886-4:2019

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2018)

Sterile Injektionskanülen für den
Einmalgebrauch - Teil 4: Spritzen mit
Vorrichtung zur Verhinderung der
Wiederverwendung (ISO 7886-4:2018)

Seringues hypodermiques stériles, non
réutilisables - Partie 4: Seringues avec
dispositif empêchant la réutilisation (ISO
7886-4:2018)

03/2019



National Foreword

This European Standard EN ISO 7886-4:2019 was adopted as Luxembourgish Standard ILNAS-EN ISO 7886-4:2019.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

THIS PUBLICATION IS COPYRIGHT PROTECTED

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

ILNAS-EN ISO 7886-4:2019

EUROPEAN STANDARD **EN ISO 7886-4**

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2019

ICS 11.040.25

Supersedes EN ISO 7886-4:2009

English Version

**Sterile hypodermic syringes for single use - Part 4:
Syringes with re-use prevention feature (ISO 7886-4:2018)**

Seringues hypodermiques stériles, non réutilisables -
Partie 4: Seringues avec dispositif empêchant la
réutilisation (ISO 7886-4:2018)

Sterile Injektionskanülen für den Einmalgebrauch -
Teil 4: Spritzen mit Vorrichtung zur Verhinderung der
Wiederverwendung (ISO 7886-4:2018)

This European Standard was approved by CEN on 1 March 2019.

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.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, 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
Endorsement notice	3

European foreword

This document (EN ISO 7886-4:2019) 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 September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 7886-4:2009.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7886-4:2018 has been approved by CEN as EN ISO 7886-4:2019 without any modification.

Sterile hypodermic syringes for single use —

Part 4: Syringes with re-use prevention feature

Seringues hypodermiques stériles, non réutilisables —

Partie 4: Seringues avec dispositif empêchant la réutilisation



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

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 Types of syringe	2
4.1 General	2
4.2 Types of re-use prevention feature	2
4.3 Types of intended use/application	2
5 Extraneous matter	2
5.1 General	2
5.2 Limits for acidity or alkalinity	2
5.3 Limits for extractable metals	2
6 Lubricant	3
7 Tolerance on graduated capacity	3
8 Graduated scale	3
8.1 Scale	3
8.2 Numbering of scale	3
8.3 Position of scale	3
8.4 Overall length of scale to nominal capacity line	3
9 Barrel	3
9.1 Dimensions	3
9.2 Barrel flanges	3
10 Plunger stopper/plunger assembly	3
10.1 Design	3
10.2 Fit of plunger stopper/plunger in the barrel	4
10.3 Fiducial line	4
11 Syringe nozzle/needle	4
11.1 Syringe with integrated needle	4
11.2 Syringe with Luer nozzle	4
12 Performance	4
12.1 Dead space	4
12.2 Freedom from air and liquid leakage	4
12.3 Re-use prevention feature	5
12.4 Performance after shipping	5
13 Packaging	5
13.1 Unit packaging and self-contained syringe units	5
13.2 Multiple unit pack	5
13.3 User packaging	5
14 Information supplied by the manufacturer	5
14.1 General	5
14.2 Syringes	5
14.2.1 General	5
14.2.2 Unit packaging	5
14.3 Multiple unit packs	6
14.3.1 General	6
14.3.2 Multiple unit packs with self-contained syringes	6
14.4 User packaging	6