

ILNAS

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

ILNAS-EN ISO 8536-9:2015

Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015)

Matériel de perfusion à usage médical -
Partie 9: Tubulures non réutilisables avec
des appareils de perfusion sous pression
(ISO 8536-9:2015)

Infusionsgeräte zur medizinischen
Verwendung - Teil 9:
Übertragungsleitungen zur einmaligen
Verwendung mit

06/2015



National Foreword

This European Standard EN ISO 8536-9:2015 was adopted as Luxembourgish Standard ILNAS-EN ISO 8536-9:2015.

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ILNAS-EN ISO 8536-9:2015

EUROPEAN STANDARD **EN ISO 8536-9**
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English Version

Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015)

Matériel de perfusion à usage médical - Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression (ISO 8536-9:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 9: Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-9:2015)

This European Standard was approved by CEN on 16 April 2015.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

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Contents

Page

European foreword3

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices5

ILNAS-EN ISO 8536-9:2015 - Preview only Copy via ILNAS e-Shop

European foreword

This document (EN ISO 8536-9:2015) has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” 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 December 2015, and conflicting national standards shall be withdrawn at the latest by December 2015.

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

This document supersedes EN ISO 8536-9:2004.

In this edition, the following changes have been made:

- the former Clause 3 on designation has been deleted;
- 5.8 has been amended and an appropriate Annex C added;
- Clause 9 on labelling was amended by addition of information regarding the usage of the symbol “XXX” according ISO 7000, Symbol 2725;
- Clause 10 on disposal has been added;
- A.4 has been amended;
- the former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;
- normative references and the Bibliography have been updated;
- document has been editorially revised..

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 8536-9:2015 has been approved by CEN as EN ISO 8536-9:2015 without any modification.

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 594-2	—	ISO 594-2:1998
ISO 7000	—	ISO 7000:2014
ISO 7864	EN ISO 7864:1995	ISO 7864:1993
ISO 8536-10	EN ISO 8536-10:2015	ISO 8536-10:2015
ISO 8536-11	EN ISO 8536-11:2015	ISO 8536-11:2015
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012