



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

ILNAS-EN ISO 8536-5:2013

Infusion equipment for medical use - Part 5: Burette infusion sets for single use, gravity feed (ISO 8536-5:2004)

Matériel de perfusion à usage médical -
Partie 5: Appareils non réutilisables de
perfusion à burette, à alimentation par
gravité (ISO 8536-5:2004)

Infusionsgeräte zur medizinischen
Verwendung - Teil 5: Infusionsgeräte mit
Dosierbehälter für Schwerkraftinfusionen
zur einmaligen Verwendung (ISO

02/2013



National Foreword

This European Standard EN ISO 8536-5:2013 was adopted as Luxembourgish Standard ILNAS-EN ISO 8536-5:2013.

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 8536-5:2013

EUROPEAN STANDARD **EN ISO 8536-5**
NORME EUROPÉENNE
EUROPÄISCHE NORM

February 2013

ICS 11.040.20

Supersedes EN ISO 8536-5:2011

English Version

**Infusion equipment for medical use - Part 5: Burette infusion
sets for single use, gravity feed (ISO 8536-5:2004)**

Matériel de perfusion à usage médical - Partie 5: Appareils
non réutilisables de perfusion à burette, à alimentation par
gravité (ISO 8536-5:2004)

Infusionsgeräte zur medizinischen Verwendung - Teil 5:
Infusionsgeräte mit Dosierbehälter für
Schwerkraftinfusionen zur einmaligen Verwendung (ISO
8536-5:2004)

This European Standard was approved by CEN on 8 January 2013.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

| | |
|---|------|
| | Page |
| Foreword..... | 3 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices..... | 4 |

ILNAS-EN ISO 8536-5:2013 - Preview only Copy via ILNAS e-Shop

Foreword

The text of ISO 8536-5:2004 has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8536-5:2013 by 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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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 8536-5:2011.

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.

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 8536-5:2004 has been approved by CEN as EN ISO 8536-5:2013 without any modification.