ILNAS

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

ILNAS-EN ISO 11608-4:2007

Pen-injectors for medical use - Part 4: Requirements and test methods for electronic and electromechanical pen-injectors (ISO 11608-4:2006)

Stylos-injecteurs à usage médical - Partie 4: Exigences et méthodes d'essai pour stylos-injecteurs électroniques et électro-mécaniques (ISO 11608-4:2006)

Pen-Injektoren zur medizinischen Anwendung - Teil 4: Anforderungen an und Prüfverfahren für elektronische und elektromechanische Pen-Injektoren (ISO

08/2007

National Foreword

This European Standard EN ISO 11608-4:2007 was adopted as Luxembourgish Standard ILNAS-EN ISO 11608-4:2007.

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

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11608-4

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English Version

Pen-injectors for medical use - Part 4: Requirements and test methods for electronic and electromechanical pen-injectors (ISO 11608-4:2006)

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This European Standard was approved by CEN on 9 August 2007.

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 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 Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 11608-4:2007: E

Foreword

The text of ISO 11608-4:2006 has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11608-4:2007 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 February 2008, and conflicting national standards shall be withdrawn at the latest by February 2008.

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.

ISO 11608-4 consists of the following parts under the general title "Pen-injectors for medical use":

— Part 1: Pen-injectors - Requirements and test methods

— Part 2: Needles - Requirements and test methods

— Part 3: Finished cartridges - Requirements and test methods

— Part 4: Requirements and test methods for electronic and electromechanical pen-injectors

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Endorsement notice

The text of ISO 11608-4:2006 has been approved by CEN as EN ISO 11608-4:2007 without any modifications.

INTERNATIONAL STANDARD

ISO 11608-4

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Pen-injectors for medical use —

Part 4: Requirements and test methods for electronic and electromechanical pen-injectors

Stylos-injecteurs à usage médical —

Partie 4: Exigences et méthodes d'essai pour stylos-injecteurs électroniques et électro-mécaniques

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