



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 11608-4:2007

ICS 11.040.25

**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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EUROPEAN STANDARD
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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)**

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 11608-4:2006)

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.

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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of an identical text or by endorsement, at the latest by February 2008, and conflicting national standards shall be withdrawn at the latest by February 2008.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

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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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