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

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

EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-EN ISO 11608-4:2007 sisaldab Euroopa standardi EN ISO 11608-4:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 30.10.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11608-4:2007 consists of the English text of the European standard EN ISO 11608-4:2007. This document is endorsed on 30.10.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

NATIONAL FOREWORD

Käsitlusala: This part of ISO 11608 specifies requirements and test methods for electromechanically driven injectors intended to be used with needles and with replaceable or non-replaceable cartridges. The injector may be for single-use or multiple-use. The injector system is intended to deliver medication to an end-user by self-administration or with assistance. This part of ISO 11608 is neither applicable for needle-free injectors (as covered in ISO 21649) nor infusion pumps (as covered in IEC 60601-2-24). This part of ISO 11608 is not applicable for devices that are capable of operating while connected to an external power supply.	**Scope:** This part of ISO 11608 specifies requirements and test methods for electromechanically driven injectors intended to be used with needles and with replaceable or non-replaceable cartridges. The injector may be for single-use or multiple-use. The injector system is intended to deliver medication to an end-user by self-administration or with assistance. This part of ISO 11608 is neither applicable for needle-free injectors (as covered in ISO 21649) nor infusion pumps (as covered in IEC 60601-2-24). This part of ISO 11608 is not applicable for devices that are capable of operating while connected to an external power supply.

ICS 11.040.25

Võtmesõnad:

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-4

August 2007

ICS 11.040.25

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.

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

First edition
2006-03-15

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

Reference number
ISO 11608-4:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 11608-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

ISO 11608 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*

Introduction

This part of ISO 11608 covers electro-mechanical driven injectors not covered by part 1 of ISO 11608. These injectors are mainly intended to administer medicinal products to humans. This part of ISO 11608 provides performance requirements regarding essential aspects of the design so that variations of such injectors are not unnecessarily restricted.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer's ability to manufacture one “lot” of injectors that conforms to the critical product attributes. These sampling plans for inspection do not intend to replace the more general manufacturing quality systems practices widely used in production, e.g. the ISO 9000 series.

Materials to be used for the construction of these injectors are not specified, as their selection, to some extent, will depend upon the design, the intended use and the manufacturing process selected by the manufacturer. All materials used in these injectors which come in contact with the end-user must be non-toxic and biocompatible. In some countries, national regulations may exist and their requirements may supersede or add up to this part of ISO 11608.

In relation to specification limits and dose accuracy, the ISO directives (Part 2, A3 and A13) require that the VIM[1] and GUM[2] principles are used and incorporated in all future standards and future revisions of existing standards. The reorganization to be done in relation to this will not affect the technical content of the standards, and only the terminology shall be changed to correspond to VIM, and the principles shall be changed to correspond to GUM.

However, with this part of ISO 11608, ISO/TC 84 has decided to await the revision of the ISO 11608 series where the principles will be incorporated in all parts to conform to applicable requirements.

Pen-injectors for medical use —

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

1 Scope

This part of ISO 11608 specifies requirements and test methods for electromechanically driven injectors intended to be used with needles and with replaceable or non-replaceable cartridges. The injector may be for single-use or multiple-use. The injector system is intended to deliver medication to an end-user by self-administration or with assistance.

This part of ISO 11608 is neither applicable for needle-free injectors (as covered in ISO 21649) nor infusion pumps (as covered in IEC 60601-2-24).

This part of ISO 11608 is not applicable for devices that are capable of operating while connected to an external power supply.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11608-1:2000, *Pen-injectors for medical use — Part 1: Pen-injectors — Requirements and test methods*

IEC 60068-2-27:1987, *Environmental testing — Part 2: Tests. Test Ea and guidance: Shock*

IEC 60068-2-30:1980, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:1988, *Edition 2: Medical electrical equipment — Part 1: General requirements for safety* (+ AMD 1:1991 + AMD. 2: 1995)

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60721-3-7:1995, *Classification of environmental conditions — Part 3: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 61000-4-2:2001, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

3 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 11608-1 and the following apply.

3.1
drive system
electromechanical mechanism responsible for expelling the dose

3.2
pen-injector
pen-injector with an electromechanical drive system

4 Symbols and abbreviated terms

See Clause 4 of ISO 11608-1:2000.

5 General requirements

See Clause 5 of ISO 11608-1:2000.

6 Test conditions

6.1 Standard atmosphere

See 6.1 of ISO 11608-1:2000.

6.2 Cool atmosphere

See 6.2 of ISO 11608-1:2000.

6.3 Hot atmosphere

See 6.3 of ISO 11608-1:2000.

7 Preconditioning of pen-injectors

7.1 Preconditioning in dry heat atmosphere

See 7.1 of ISO 11608-1:2000.

7.2 Preconditioning in cold storage atmosphere

See 7.2 of ISO 11608-1:2000.