Pen-injectors for medical use - Part 3: Finished cartridges - Requirements and test methods

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11608-3:2001 sisaldab Euroopa standardi EN ISO 11608-3:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 18.05.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11608-3:2001 consists of the English text of the European standard EN ISO 11608-3:2000. This document is endorsed on 18.05.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies performance and test methods for multidose, single-chamber, pre-filled, finished cartridges used as primary containers in pen-injectors fulfilling the specifications of ISO 11608-1.	**Scope:** This International Standard specifies performance and test methods for multidose, single-chamber, pre-filled, finished cartridges used as primary containers in pen-injectors fulfilling the specifications of ISO 11608-1.

ICS 11.040.20

Võtmesõnad: heavy duty series., marking, medical equipment, parenteral infusion equipment, pen-injectors, performance, specifications, surgical needles, technical data sheets, tests

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Pen-injectors for medical use

Part 3: Finished cartridges – Requirements and test methods
(ISO 11608-3 : 2000)

Stylos-injecteurs à usage médical – Partie 3: Cartouches prêtes à l'emploi – Exigences et méthodes d'essai (ISO 11608-3 : 2000)

Pen-Injektoren zur medizinischen Anwendung – Teil 3: Fertigkarpulen – Anforderungen und Prüfverfahren (ISO 11608-3 : 2000)

This European Standard was approved by CEN on 2000-12-01.

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 Management Centre or to any CEN member.

The European Standards exist 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

International Standard

ISO 11608-3 : 2000 Pen-injectors for medical use – Part 3: Finished cartridges – Requirements and test methods,

which was prepared by ISO/TC 84 'Medical devices for injections' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 205 'Non-active medical devices', the Secretariat of which is held by BSI, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by June 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11608-3 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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Introduction

This part of ISO 11608 covers finished cartridges filled with medicinal products primarily intended for human use. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted.

The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-1 and ISO 11608-2.

It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and to be avoided for other medicinal products, and that future designs may change the current concepts. Therefore ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

Performance requirements are imposed on both interchangeable (Type A) and non-interchangeable (non-Type A) cartridges. Additional dimensional requirements are imposed on interchangeable cartridges (Type A).

Information as to whether the components are interchangeable (Type A) or not will be given on the secondary container.

It is desirable that non-Type A cartridges do not fit pen-injectors intended for type A cartridges.

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 finished cartridges that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, e.g. the ISO 9000 series.

Regulatory authorities, pharmacopoeia and relevant trade associations should recognize the need for further testing, especially regarding compatibility between the medicinal products and cartridge as they are in contact for prolonged periods.

In some countries, national pharmacopoeia or government regulations exist and their requirements may take precedence over or complement this part of ISO 11608. In particular, materials in contact with the medicinal product shall comply with all relevant pharmacopoeia requirements.

1 Scope

This part of ISO 11608 specifies performance and test methods for multidose, single-chamber, pre-filled, finished cartridges used as primary containers in pen-injectors fulfilling the specifications of ISO 11608-1. Design and dimensions are specified for Type A cartridges.

This part of ISO 11608 is not applicable to multichamber cartridges, cartridges that are filled by the user, and cartridges intended for dental use.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11608. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11608 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3207, *Statistical interpretation of data — Determination of a statistical tolerance interval.*

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

ISO 13926-1:1998, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use.*

3 Terms and definitions

For the purposes of this part of ISO 11608, the following terms and definitions apply.

The nomenclature of some of the cartridge components is illustrated in Figure 1.

3.1
cartridge
primary container for the medicinal product

3.2
unit container
package intended for customer use

3.3
cylinder
main body of the cartridge