SLOVENSKI STANDARD
SIST EN ISO 11608-2:2001

01-november-2001

Peresa za injiciranje za uporabo v medicini - 2. del: Igle - Zahteve in preskusne metode (ISO 11608-2:2000)

Pen-injectors for medical use - Part 2: Needles - Requirements and test methods (ISO 11608-2:2000)

Pen-Injektoren zur medizinischen Anwendung - Teil 2: Kanülen -Anforderungen und Prüfverfahren (ISO 11608-2:2000)

Stylos-injecteurs a usage médical - Partie 2: Aiguilles -Exigences et méthodes d'essai (ISO 11608-2:2000)

Ta slovenski standard je istoveten z: **EN ISO 11608-2:2000**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 11608-2:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 11608-2

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English version

Pen-injectors for medical use - Part 2: Needles - Requirements and test methods (ISO 11608-2:2000)

Stylos-injecteurs à usage médical - Partie 2: Aiguilles - Exigences et méthodes d'essai (ISO 11608-2:2000)

Pen-Injektoren zur medizinischen Anwendung - Teil 2: Kanülen - Anforderungen und Prüfverfahren (ISO 11608-2:2000)

This European Standard was approved by CEN on 1 December 2000.

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.

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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, 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 11608-2:2000 E

Foreword

The text of the International Standard ISO 11608-2:2000 has been prepared by Technical Committee ISO/TC 84 "Medical devices for injections" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

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 June 2001, and conflicting national standards shall be withdrawn at the latest by June 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11608-2:2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)
Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 6009	1992	Hypodermic needles for single use – Colour coding for identification	EN ISO 6009	1994
ISO 7864	1993	Sterile hypodermic needles for single use	EN ISO 7864	1995
ISO 9626	1991	Sterile hypodermic needles for single use	EN ISO 9626	1995
ISO 11608-1	2000	Pen-injectors for medical use – Part 1: Pen-injectors – Requirements and test methods	EN ISO 11608-1	2000
IEC 60068-2-30	1980	Environmental testing – Part 2: Tests – Test Db and guidance: Damp heat cyclic (12 + 12 - hour cycle)	EN 60068-2-30	1980

INTERNATIONAL STANDARD

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Part 2: Needles — Requirements and test methods

Stylos-injecteurs à usage médical —

Partie 2: Aiguilles — Exigences et méthodes d'essai

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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 3.

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 part of ISO 11608 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11608-2 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*.

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*

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with pen-injectors.

The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-1 and ISO 11608-3.

It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and should be avoided for other medicinal products, and that future design 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) needles. Additional dimensional requirements are imposed on interchangeable needles (Type A).

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

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

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 needles 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.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards, because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological tests relevant to double-ended needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such evaluation should include the effects of the process whereby the needles are sterilized. However, national regulations may exist in some countries, and these may take precedence over the guidance in ISO 10993-1.

In some countries, national regulations exist and their requirements may supersede or complement this part of ISO 11608.