SLOVENSKI STANDARD
oSIST prEN ISO 11608-5:2011

01-februar-2011

Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 5. del: Avtomatizirane funkcije (ISO/DIS 11608-5:2010)

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO/DIS 11608-5:2010)

Nadelbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 5: Automatisierte Funktionen (ISO/DIS 11608-5:2010)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 5: Fonctions automatisées (ISO/DIS 11608-5:2010)

Ta slovenski standard je istoveten z: **prEN ISO 11608-5**

ICS:

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

oSIST prEN ISO 11608-5:2011 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO/DIS 11608-5:2010)

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This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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Foreword

This document (prEN ISO 11608-5:2010) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 11608-5:2010 has been approved by CEN as a prEN ISO 11608-5:2010 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 11608-5

ISO/TC **84** Secretariat: **DS**

Voting begins on: **2010-10-28**

Voting terminates on: **2011-03-28**

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Needle-based injection systems for medical use — Requirements and test methods —

Part 5: Automated functions

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 5: Fonctions automatisées

ICS 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 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 11608-5 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 *Needle-based injection systems for medical use — Requirements and test methods*:

— *Part 1: Needle-based injection systems*

— *Part 2: Needles*

— *Part 3: Finished cartridges and syringes*

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

— *Part 5: Automated functions*

Introduction

This standard applies to Needle Injection Systems with Automated functions (NIS-AUTO) primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of of NIS-AUTOs, this standard is promulgated more as a “horizontal” than “vertical” one. Thus, it will tend to specify the results of the design effort instead of the physical and construction requirements used as the basis for NIS-AUTO design, so that innovation in achieving the intended purposes is not unnecessarily restricted.

These standards intentionally avoid addressing more than the most basic elements regarding the safety and performance of needle-based injection systems with automated functions in humans. Any intended labelling of such NIS-AUTOs indicating their use to deliver medicinal products into the body or into specified tissue strata thereof (e.g., intramuscular, subcutaneous, or intradermal), or for the administration of specific pharmaceutical drugs or vaccines shall fall under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical NIS-AUTOs and pharmaceutical products. These standards are expected to be supplemented by additional requirements and may occasionally be superseded by such regulatory authorities. Despite certain advantages for intentional interchangeability for containers designed for different auto-injection systems, as well as the potential risks of inadvertent interchangeability, these standards avoid setting forth design specifications for the uniform size, shape, and interface of such containers. This issue is left for future initiatives to build upon the standards promulgated herein.

The sampling plans for inspection selected for this standard are intended to verify the design, at a high confidence level. The sampling plan does not replace the more general manufacturing quality systems, including lot release, which appear in standards on quality systems, e.g. the ISO 9000 series or ISO 13485.

All references to function in this standard are by definition to be construed as automated functions (defined). This standard does not apply to these functions if they are performed manually by the user.