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Medicintekniska injektionspennor – Krav och provningsmetoder – Del 5: Automatiska funktioner (ISO 11608-5:2012)

Needle-based injection systems for medical use – Requirements and test methods – Part 5: Automated functions (ISO 11608-5:2012)

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The European Standard EN ISO 11608-5:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 11608-5:2012.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 11608-5:2012/ Relations to other parts under the same general title - Extract from the Foreword of ISO 11608-5:2012

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 containers*
- *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*
- *Part 5: Automated functions*

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-5

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ICS 11.040.25

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2012)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 5: Fonctions automatisées (ISO 11608-5:2012)

Nadelbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 5: Automatisierte Funktionen (ISO 11608-5:2012)

This European Standard was approved by CEN on 29 September 2012.

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Contents

Page

Foreword

This document (EN ISO 11608-5:2012) 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 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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 11608-5:2012 has been approved by CEN as a EN ISO 11608-5:2012 without any modification.

Introduction

This part of ISO 11608 is applicable to needle-based injection systems with automated functions (NIS-AUTO), primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of NIS-AUTOs, this part of ISO 11608 is promulgated more as a “horizontal” than a “vertical” standard. Thus, it tends 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.

This part of ISO 11608 intentionally avoids addressing more than the most basic elements regarding the safety and performance of NIS-AUTOs 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, falls under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical NIS-AUTOs and pharmaceutical products.

This part of ISO 11608 is expected to be supplemented by additional requirements and might 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, this part of ISO 11608 avoids setting forth design specifications for the uniform size, shape and interface of such containers. It is left for future initiatives to build upon the specifications in this part of ISO 11608.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify the design, at a high confidence level. The sampling plan does not replace more general manufacturing quality systems, including lot release, which are addressed in standards on quality management systems, for example the ISO 9000 series or ISO 13485.

All references to “function” in this part of ISO 11608 are by definition to be construed as automated functions (see 3.4). This part of ISO 11608 does not apply to these functions if they are performed manually by the user.

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

Part 5: Automated functions

1 Scope

This part of ISO 11608 specifies requirements and test methods for the automated functions of needle-based injection systems with automated functions (NIS-AUTO), for the administration of medicinal products in humans, including but not limited to:

a) drug product preparation (e.g. reconstitution);

b) needle preparation;

c) air removal;

d) priming;

e) dose setting;

f) actuation;

g) needle insertion;

h) injection of the medicinal product;

i) disabling the NIS-AUTO;

j) needle retraction;

k) needle shielding;

l) needle hiding;

m) sharps injury protection;

n) needle removal.

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, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accessory
article or supplementary part used for convenience or safety in conjunction with a NIS-AUTO

EXAMPLES Magnifying lens to aid reading of dose setting, grip enhancer, dose counter of a NIS-AUTO.

3.2
actuation
action which initiates a NIS-AUTO function (e.g. needle insertion), triggered by the actions of the NIS-AUTO user (or by another automated function)

EXAMPLE Pressing the NIS-AUTO against the injection site.

3.3
air removal
action to remove air from the container and/or needle of the NIS-AUTO

3.4
automated function
function which does not require user initiation after actuation

NOTE A dose counter is considered an automated function if it is initiated by, for example, an automated needle retraction step, and therefore changes its state without any user interference.

3.5
injection
delivery of the dose to the intended injection depth

3.6
intended injection depth
range of injection depth to which the drug is intended to be delivered

See Figure 1.

3.7
needle-based injection system with automated functions
NIS-AUTO
injection system that delivers a medication through a needle wherein one or a series of functions are initiated by an action of the user and controlled automatically by the injection system

NOTE Accessories that perform automatic functions in combination with manual injection NIS-AUTOs are regarded as NIS-AUTO.

3.8
needle cover
cover provided over a needle in order to protect the needle from damage and users from injury prior to use of the needle

3.9
needle extension
axial distance from the patient end of the needle tip to the nearest part of the NIS-AUTO body (defining the point of contact with the patient adjacent to the injection site)

3.10
needle hiding
function which obscures the needle from the user's sight either before, during or after the injection cycle

NOTE The needle hiding function only has a visual requirement designed to reduce patient trauma in case of needle phobia. It is not subject to any physical or dimensional requirements intended to restrict access to the needle. It does not imply any increased level of safety from needle stick injuries.

3.11
insertion of needle
function which inserts the needle into the patient's skin to the intended injection depth prior to the injection of the medicinal product

3.12
needle shielding
function which covers the exposed needle before and/or after the injection cycle to reduce the likelihood of direct contact with the needle

NOTE 1 Needle shielding can reduce the risk of damage and contamination of the needle before use and can cover the needle after use.

NOTE 2 Needle shielding does not meet the requirements of a sharps injury protection feature unless it complies with ISO 23908.

3.13
priming
function that makes the dosing mechanism of the NIS-AUTO ready for actuation

3.14
retraction of needle
function which removes the needle from the target tissue to a predefined minimum needle point position inside the NIS-AUTO

3.15
risk assessment
RA
overall process comprising a risk analysis (estimation) and a risk evaluation

NOTE Adapted from ISO 14971:2007, definition 2.18.

3.16
sharps injury protection feature
function that prevents accidental sharps injury

NOTE The NIS-AUTO might provide an active or passive automated function (definitions of active and passive safety features are given in ISO 23908), distinct from needle shielding or hiding, which is designed to minimize the risks of accidental sharps injury. The NIS-AUTO cannot claim to have sharps injury protection unless it meets the requirements of ISO 23908.

3.17
target tissue
location in the body into which the medicinal product is delivered and that defines the route of administration

NOTE Parts of the body for this part of ISO 11608 can include the dermis, subcutaneous tissue and muscle.

4 Requirements

4.1 General requirements

a) The NIS-AUTO shall be designed to avoid unintended actuation.

b) The NIS-AUTO shall perform its intended automated functions when tested following pre-conditioning (including free fall) in accordance with ISO 11608-1.