BS EN ISO 11608-2:2012

BSI Standards Publication

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

Part 2: Needles (ISO 11608-2:2012)

This British Standard is the UK implementation of EN ISO 11608-2:2012. It supersedes BS EN ISO 11608-2:2001 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles (ISO 11608-2:2012)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 2: Aiguilles (ISO 11608-2:2012)

Nadelbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 2: Nadeln (ISO 11608-2:2012)

This European Standard was approved by CEN on 31 March 2012.

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Foreword

This document (EN ISO 11608-2:2012) 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of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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.

This document supersedes EN ISO 11608-2:2000.

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Endorsement notice

The text of ISO 11608-2:2012 has been approved by CEN as a EN ISO 11608-2:2012 without any modification.

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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.

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ISO 11608-2 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 11608-2:2000), which has been technically revised.

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*

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with needle-based injection systems (e.g. pen injectors). These needles are often referred to as pen needles.

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

The first edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designations “Type A” (i.e.interchangeable) and “non-Type A” for needles and container closure systems. Since its promulgation, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in the different parts of this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. Based on this experience, it is believed that the Type A designation does not represent adequate guidance to the user in making decisions on the compatibility of needles and container closures with specific needle-based injection systems (NIS). As such, the labelling designation “Type A” has been removed.

This second edition of ISO 11608-2 addresses functional compatibility of the system through testing in accordance with Clause 11. Flow rate is introduced as a new parameter. 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, for example ISO 9000.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards because no international agreement on the methodology and the pass/fail criteria has been reached. 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 sterilization process. However, national regulations might exist in some countries, which might take precedence over the guidance in ISO 10993-1.

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

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

Part 2: Needles

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

It is not applicable to:

— needles for dental use;

— pre-filled syringe needles;

— needles pre-assembled by the manufacturer;

— needles not requiring assembly or attachment to the NIS.

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 7864:1993, *Sterile hypodermic needles for single use*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 11608-1, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

3 Terms and definitions

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

3.1
NIS
needle-based injection system
system intended for parenteral administration by injection of medicinal products using a multi-dose or single-dose container

See Figure 1.