BS EN ISO 11608-5:2012

BSI Standards Publication

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

Part 5: Automated functions (ISO 11608-5:2012)

This British Standard is the UK implementation of EN ISO 11608-5:2012.

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.

ISBN 978 0 580 69949 8

ICS 11.040.25

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2012.

Amendments issued since publication

Date	Text affected

EUROPÄISCHE NORM

October 2012

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.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11608-5:2012: E

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.

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 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.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clauses 4.1 to 4.3, all parts	1	Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.1 to 4.4, all parts	2	Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.1 to 4.3, 5, 6, all parts	3	All clauses of ISO 11608-1 are applicable
NA	4	
NA	5	
Clause 4.1 parts E and G, clause 4.3 all parts	6	
Clauses 4.2.2 and 5.1.1	7	Only 7.3 is addressed
Clause 4.1 parts D	8	Only 8.3 is addressed
Clauses 4.1 to 4.4, all parts	9	9.3 is not addressed Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.2.5, 4.3.3.3, 4.3.5.1, 5.1.4, 5.1.7, 5.1.8.1 and 5.2	10	All clauses of ISO 11608-1 are applicable
NA	11	
NA	12	
Clause 7	13	13.5 is not addressed Clause 5.4, part D and Q and Clause 13, all parts of ISO 11608-1 address ER 13

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

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 containers*

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

— *Part 5: Automated functions*

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*