BSI Standards Publication

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

Part 7: Accessibility for persons with visual impairment

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 11608-7:2017. It is identical to ISO 11608-7:2016.

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.

Published by BSI Standards Limited 2020

ISBN 978 0 539 13447 6

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 2017.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2020	Annex ZA added

EUROPEAN STANDARD **EN ISO 11608-7**

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2017

ICS 11.040.25

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment (ISO 11608-7:2016)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 7: Accessibilité pour les personnes malvoyantes (ISO 11608-7:2016)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 7: Anforderungen an die Barrierefreiheit für Menschen mit Sehbehinderung (ISO 11608-7:2016)

This European Standard was approved by CEN on 9 July 2017.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

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Ref. No. EN ISO 11608-7:2017 E

European foreword

The text of ISO 11608-7:2016 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11608-7:2017 by 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 February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN 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(s).

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11608-7:2016 has been approved by CEN as EN ISO 11608-7:2017 without any modification.

The following referenced documents are indispensable for the application of this document.

For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table – Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	**Equivalent dated standard**	
	EN	**ISO or IEC**
ISO 11608-1:2014	EN ISO 11608-1:2015	ISO 11608-1:2014
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
IEC 62366-1	EN 62366-1:2015 + AC:2015	IEC 62366-1:2015 + Cor 1:2016

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/295 concerning the development of European standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 – Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN ISO 11608-7	**Remarks/Notes**
7.2	4.2.2	Clause 4.2.2 of the standard only meets the requirements or ER 7.2 in respect of packaging design, and then only for opening the packaging, and spillage of the contents.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Contents

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and 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: Needle-based injection systems containing electronics*

— *Part 5: Automated functions*

— *Part 6: On-body delivery systems*

— *Part 7: Accessibility for persons with visual impairment*

Introduction

Prior to this part of ISO 11608, the ISO 11608 series has not provided guidance to address the use of NIS by persons with visual impairment. The reality, however, is that a significant number of NIS users have visual impairments and operate these devices, even though the user interfaces rely primarily on visual communication to provide the information needed for safe and effective use. The result is that users with visual impairment have difficulty and may be at greater risk when using these products.

Given the prevalence of visual impairment and the fact that many NIS target disease states (e.g. diabetes) with co-morbid conditions that can impair vision, efforts should be made to eliminate or minimize, where possible, device features that constitute obstructions to product use for users with visual impairment.

This part of ISO 11608 defines terms related to visual impairment and provides guidance to enable manufacturers to provide information to the user in other sensory formats (e.g. tactile, auditory). New and existing features that address the needs of users with visual impairment will also benefit a broader population.

The purpose of this part of ISO 11608 is to assist manufacturers in developing NIS designs that will be usable for users with visual impairment but recognizes that those designs could be more usable also for users with no visual impairment. Taking this type of "universal design"[29] approach is preferable to the creation of "niche" products only for users with visual impairment, for which the market would be smaller and, consequently, the product cost likely would be higher. Applying universal design principles to extend access to users with visual impairment can increase the market size, thereby reducing product cost and enabling a broader patient population to access the NIS.

For product design purposes, it should be assumed that some users will have moderate visual impairment but will be able to read large print and see high-contrast product features. Other users, however, will not be able to make use of any visual features and will instead require information to be provided through other sensory means (e.g. tactile or auditory). Therefore, this part of ISO 11608 includes the requirement to provide information in visual formats that can be perceived and understood by people with moderate visual impairment and in non-visual formats (e.g. tactile or auditory) that can be perceived and understood by people with no useful vision.

In conjunction with other parts of the ISO 11608 series, manufacturers are expected to follow a risk-based approach and employ human factors engineering during the design, development, and manufacture of NIS serving this important user population. Existing products and those currently under development may not fulfil some of the requirements given by this part of ISO 11608. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain a higher level of accessibility.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

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

Part 7: Accessibility for persons with visual impairment

1 Scope

This part of ISO 11608 specifies particular requirements to make needle-based drug delivery systems or NIS (needle-based injection system) accessible for persons with visual impairments. It applies to devices intended for patient or caregiver administration of medicinal products to humans.

This part of ISO 11608 covers requirements to allow for safe and correct handling of the NIS, including labelling, packaging, and instructions for use. It also includes requirements for training programs, if applicable.

This part of ISO 11608 covers requirements for NIS that are claimed to be appropriate for use by persons with visual impairments.

This part of ISO 11608 does not address requirements for use of sharps containers by persons with visual impairments.

Although specifically intended to apply to needle-based injection systems within the ISO 11608 series, this part of ISO 11608 can be applied to NIS outside the ISO 11608 series as well, if they might be used by persons with visual impairments.

This part of ISO 11608 is written to address the needs of persons with all levels of visual limitations, including low, moderate, or severe visual impairment; legal, functional, or total blindness; and colour vision deficiencies.

Therefore, this part of ISO 11608 includes the requirement to provide information in visual formats that can be perceived and understood by people with moderate visual impairment and in non-visual formats (e.g. tactile or auditory) that can be perceived and understood by people with no useful vision.

For simplicity's sake, this range is described in this part of ISO 11608 as addressing the needs of individuals with moderate visual impairment or blindness.

NOTE NIS that are not claimed to be appropriate for use by persons with visual impairments need not meet these requirements, but manufacturers are encouraged to consider them.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11608-1:2014, *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 62366-1,[1)] *Medical devices — Part 1: Application of usability engineering to medical devices*

1) Replaces IEC 62366.