

BS EN ISO 11608-1:2015



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

Part 1: Needle-based injection systems

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National foreword

This British Standard is the UK implementation of EN ISO 11608-1:2015. It is identical to ISO 11608-1:2014. It supersedes BS EN ISO 11608-1:2012 which is withdrawn.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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Amendments issued since publication

Date	Text affected
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English Version

**Needle-based injection systems for medical use - Requirements
and test methods - Part 1: Needle-based injection systems (ISO
11608-1:2014)**

Systèmes d'injection à aiguille pour usage médical -
Exigences et méthodes d'essai - Partie 1: Systèmes
d'injection à aiguille (ISO 11608-1:2014)

Kanülenbasierte Injektionssysteme zur medizinischen
Verwendung - Anforderungen und Prüfverfahren - Teil 1:
Kanülenbasierte Injektionssysteme (ISO 11608-1:2014)

This European Standard was approved by CEN on 11 October 2014.

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Foreword

This document (EN ISO 11608-1:2015) has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and 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of an identical text or by endorsement, at the latest by July 2015, and conflicting national standards shall be withdrawn at the latest by July 2015.

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This document supersedes EN ISO 11608-1:2012.

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.

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Endorsement notice

The text of ISO 11608-1:2014 has been approved by CEN as EN ISO 11608-1:2015 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, 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 normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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