BSI Standards Publication

Sterile single-use intravascular introducers, dilators and guidewires

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 11070:2014+A1:2018. It is identical to ISO 11070:2014, incorporating amendment 1:2018. It supersedes BS EN ISO 11070:2014, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

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.

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

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Amendments/corrigenda issued since publication

Date	Text affected
31 July 2018	Implementation of ISO amendment 1:2018 with CEN endorsement A1:2018
30 September 2018	Implementation of CEN correction notice 15 August 2018: supersession information in Foreword to amendment A1 amended
30 November 2018	Implementation of CEN correction notice 31 October 2018: supersession information in Foreword to amendment A1 deleted

EUROPEAN STANDARD EN ISO 11070:2014
NORME EUROPÉENNE

EUROPÄISCHE NORM July 2018

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English Version

Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014)

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables (ISO 11070:2014)

Sterile Einführungsinstrumente, Dilatatoren und Führungsdrähte zur einmaligen Verwendung (ISO 11070:2014)

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European foreword

This document (EN ISO 11070:2014) 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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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Endorsement notice

The text of ISO 11070:2014 has been approved by CEN as EN ISO 11070:2014 without any modification.

Foreword to amendment A1

This document (EN ISO 11070:2014/A1:2018) 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 January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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Endorsement notice

The text of ISO 11070:2014/Amd 1:2018 has been approved by CEN as EN ISO 11070:2014/A1:2018 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.

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).

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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*.

This second edition cancels and replaces the first edition (ISO 11070:1998), which has been technically revised.

Introduction

The purpose of this International Standard is to

— update requirements and test methods to support the function of the guidewire, and

— update size designation.

Sterile single-use intravascular introducers, dilators and guidewires

1 Scope

This International Standard specifies requirements for introducer needles, introducer catheters, sheath introducers, guidewires, and dilators supplied in the sterile condition, and intended for single use in conjunction with intravascular catheters specified in ISO 10555-1.

NOTE Guidance on materials and design of accessory devices is given in Annex A.

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 594-1[1)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2[2)], *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

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

NOTE Schematic examples of the devices covered by this International Standard, with examples of terminology, are given for information in Figure 1, Figure 2, Figure 3, and Figure 4.

3.1
coil (of a guidewire)
helically wound wire

3.2
core wire (of a guidewire)
wire used to achieve stiffness of the *guidewire* (3.6)

3.3
dilator
flexible, tubular device used for dilating the percutaneous opening into a blood vessel

1) Upon its publication, ISO 80369-7 will replace ISO 594-1:1986.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2:1998.