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STN	**Sterilné zavádzače intravaskulárnych katétrov na jednorazové použitie (ISO 11070:2014).**	**STN EN ISO 11070** 85 5835

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/15

Obsahuje: EN ISO 11070:2014, ISO 11070:2014

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11070

November 2014

ICS 11.040.25

Supersedes EN ISO 11070:1999

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)

This European Standard was approved by CEN on 30 August 2014.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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.

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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.

INTERNATIONAL STANDARD

ISO 11070

Second edition
2014-11-01

Sterile single-use intravascular introducers, dilators and guidewires

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables

Reference number
ISO 11070:2014(E)

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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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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.

INTERNATIONAL STANDARD ISO 11070:2014(E)

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*

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.