ICS 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA Január 2019

STN	**Sterilné zavádzače intravaskulárnych katétrov na jednorazové použitie (ISO 11070:2014) Zmena A1**	**STN EN ISO 11070/A1** 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. 12/18

Obsahuje: EN ISO 11070:2014/A1:2018, ISO 11070:2014/Amd 1:2018

127493

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11070:2014/A1

July 2018

ICS 11.040.25

English Version

Sterile single-use intravascular introducers, dilators and guidewires - Amendment 1 (ISO 11070:2014/Amd 1:2018)

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables - Amendement 1 (ISO 11070:2014/Amd 1:2018)

Sterile Einführungsinstrumente, Dilatatoren und Führungsdrähte zur einmaligen Verwendung - Änderung 1 (ISO 11070:2014/Amd 1:2018)

This amendment A1 modifies the European Standard EN ISO 11070:2014; it was approved by CEN on 3 July 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11070:2014/A1:2018 E

Contents

Page

European foreword

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.

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.

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 11070:2014/Amd 1:2018 has been approved by CEN as EN ISO 11070:2014/A1:2018 without any modification.

INTERNATIONAL STANDARD

ISO 11070

Second edition
2014-11-01

AMENDMENT 1
2018-05

Sterile single-use intravascular introducers, dilators and guidewires

AMENDMENT 1

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables

AMENDEMENT 1

Reference number
ISO 11070:2014/Amd.1:2018(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

ISO 11070:2014/Amd.1:2018(E)

Sterile single-use intravascular introducers, dilators and guidewires

AMENDMENT 1

8.6