

**SLOVENSKI STANDARD**  
**SIST EN ISO 11070:2015/A1:2018**  
**01-september-2018**

---

**Sterilni žilni instrumenti za enkratno uporabo - Dopolnilo A1 (ISO 11070:2014/Amd 1:2018)**

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

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

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

<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>

**Ta slovenski standard je istoveten z: EN ISO 11070:2014/A1:2018**

---

**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
-----------	-------------------------------------	---------------------------------

**SIST EN ISO 11070:2015/A1:2018**      **en**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 11070:2015/A1:2018

<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>

EUROPEAN STANDARD

EN ISO 11070:2014/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2018

ICS 11.040.25

English Version

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

Introduceurs, 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.

**iTeh STANDARD PREVIEW**

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**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 11070:2015/A1:2018](https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018)  
<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>

## 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.

This document supersedes EN 1617:1997.

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.

**iTeh STANDARD PREVIEW**  
**Endorsement notice**  
**(standards.iteh.ai)**

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

<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

SIST EN ISO 11070:2015/A1:2018

<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>

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*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 11070:2015/A1:2018](https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018)

[https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-  
d1a019075b63/sist-en-iso-11070-2015-a1-2018](https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018)



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

© ISO 2018

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 11070:2015/A1:2018](https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018)

<https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://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](http://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](http://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](http://www.iso.org/iso/foreword.html).

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

[SIST EN ISO 11070:2015/A1:2018  
https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018](https://standards.iteh.ai/catalog/standards/sist/6c6bd138-2cd5-42d1-b35d-d1a019075b63/sist-en-iso-11070-2015-a1-2018)