

<b>STN</b>	<b>Sterilné zavadzače intravaskulárnych katétrov na jednorazové použitie (ISO 11070:2014).</b>	<b>STN EN ISO 11070</b>  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  
STN EN ISO 11070 (85 5835) z mája 2001

**120672**

English Version

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

Introduceurs, dilateurs et guides intravasculaires stériles  
non réutilisables (ISO 11070:2014)

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

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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 European Standard 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, 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: Avenue Marnix 17, B-1000 Brussels**

**Contents**

**page**

**Foreword.....3**

## **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.

This document supersedes EN ISO 11070:1999.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### **Endorsement notice**

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

---

---

## **Sterile single-use intravascular introducers, dilators and guidewires**

*Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables*





**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2014

All rights reserved. Unless otherwise specified, 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  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>5</b>
4.1 Sterilization.....	5
4.2 Biocompatibility.....	5
4.3 Surface.....	5
4.4 Corrosion resistance.....	5
4.5 Radio-detectability.....	5
4.6 Information to be supplied by the manufacturer.....	5
<b>5 Additional requirements for introducer needles</b> .....	<b>6</b>
5.1 General.....	6
5.2 Size designation.....	6
5.3 Needle point.....	6
5.4 Hub.....	6
5.5 Information to be supplied by the manufacturer.....	6
<b>6 Additional requirements for introducer catheters</b> .....	<b>6</b>
6.1 General.....	6
6.2 Tip.....	7
6.3 Peak tensile force.....	7
6.4 Hub.....	7
6.5 Size designation.....	7
6.6 Information to be supplied by the manufacturer.....	8
<b>7 Additional requirements for sheath introducers</b> .....	<b>8</b>
7.1 General.....	8
7.2 Size designation.....	8
7.3 Freedom from leakage from sheath introducer.....	8
7.4 Freedom from leakage through haemostasis valve.....	8
7.5 Hub.....	8
7.6 Peak tensile force.....	8
7.7 Information to be supplied by the manufacturer.....	8
<b>8 Additional requirements for guidewires</b> .....	<b>8</b>
8.1 General.....	8
8.2 Size designation.....	9
8.3 Safety wire.....	9
8.4 Fracture test.....	9
8.5 Flexing test.....	9
8.6 Peak tensile force of guidewire.....	9
8.7 Information to be supplied by the manufacturer.....	10
<b>9 Additional requirements for dilators</b> .....	<b>10</b>
9.1 General.....	10
9.2 Size designation.....	10
9.3 Hub.....	10
9.4 Information to be supplied by the manufacturer.....	10
<b>10 Additional requirements for kits containing combinations of devices specified in this International Standard</b> .....	<b>10</b>
<b>Annex A (informative) Guidance on materials and design</b> .....	<b>12</b>

<b>Annex B</b> (normative) <b>Test method for corrosion resistance</b> .....	<b>13</b>
<b>Annex C</b> (normative) <b>Method for determining peak tensile force of introducer catheters, sheath introducers, and dilators</b> .....	<b>14</b>
<b>Annex D</b> (normative) <b>Test method for liquid leakage from sheath introducers under pressure</b> .....	<b>16</b>
<b>Annex E</b> (normative) <b>Test method for liquid leakage through haemostasis valves of sheath introducers</b> .....	<b>18</b>
<b>Annex F</b> (normative) <b>Test method for fracture of guidewires</b> .....	<b>19</b>
<b>Annex G</b> (normative) <b>Test method for resistance of guidewires to damage by flexing</b> .....	<b>21</b>
<b>Annex H</b> (normative) <b>Method for determining peak tensile force of guidewires</b> .....	<b>23</b>
<b>Annex I</b> (normative) <b>Determination of strength of union of needle hub and needle</b> .....	<b>25</b>
<b>Bibliography</b> .....	<b>26</b>



## 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 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<sup>1)</sup>, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2<sup>2)</sup>, *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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**

---

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.