



SLOVENSKI STANDARD
SIST EN ISO 10555-6:2017/A1:2019

01-december-2019

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 6. del: Podkožni vsadki - Dopolnilo A1 (ISO 10555-6:2015/Amd 1:2019)

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports - Amendment 1 (ISO 10555-6:2015/Amd 1:2019)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung — Teil 6: Subkutan implantierte Ports - Änderung 1 (ISO 10555-6:2015/Amd 1:2019)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 6: Chambres à cathéter implantables - Amendement 1 (ISO 10555-6:2015/Amd 1:2019)

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Ta slovenski standard je istoveten z: EN ISO 10555-6:2017/A1:2019

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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SIST EN ISO 10555-6:2017/A1:2019 **en**

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EUROPEAN STANDARD

EN ISO 10555-6:2017/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2019

ICS 11.040.25

English Version

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports - Amendment 1 (ISO 10555-6:2015/Amd 1:2019)

Cathéters intravasculaires - Cathéters stériles et non
réutilisables - Partie 6: Chambres à cathéter
implantables - Amendement 1 (ISO 10555-
6:2015/Amd 1:2019)

Intravaskuläre Katheter - Sterile Katheter zur
einmaligen Verwendung - Teil 6: Subkutan
implantierte Ports - Änderung 1 (ISO 10555-
6:2015/Amd 1:2019)

This amendment A1 modifies the European Standard EN ISO 10555-6:2017; it was approved by CEN on 6 September 2019.

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.

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

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

Contents	Page
European foreword.....	3

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[SIST EN ISO 10555-6:2017/A1:2019](https://standards.iteh.ai/catalog/standards/sist/4a98bec0-0f01-4848-871e-c6420b00ac38/sist-en-iso-10555-6-2017-a1-2019)
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European foreword

This document (EN ISO 10555-6:2017/A1:2019) 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 Amendment to the European Standard EN ISO 10555-6:2017 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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The text of ISO 10555-6:2015/Amd 1:2019 has been approved by CEN as EN ISO 10555-6:2017/A1:2019 without any modification.

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<https://standards.iteh.ai/catalog/standards/sist/4a98bec0-0f01-4848-871e-c6420b00ac38/sist-en-iso-10555-6-2017-a1-2019>

INTERNATIONAL
STANDARD

ISO
10555-6

First edition
2015-04-15

AMENDMENT 1
2019-09

**Intravascular catheters — Sterile and
single-use catheters —**

Part 6:
Subcutaneous implanted ports

AMENDMENT 1

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Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 6: Chambres à cathéter implantables

AMENDEMENT 1

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Foreword

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

A list of all parts in the ISO 10555 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.