SLOVENSKI STANDARD
SIST EN ISO 10555-1:2013/A1:2018

01-februar-2018

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve - Dopolnilo A1 (ISO 10555-1:2013/Amd 1:2017)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1 (ISO 10555-1:2013/Amd 1:2017)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen - Änderung 1 (ISO 10555-1:2013/DAmd 1:2016)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales - Amendement 1 (ISO 10555-1:2013/DAmd 1:2016)

Ta slovenski standard je istoveten z: **EN ISO 10555-1:2013/A1:2017**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 10555-1:2013/A1:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1:2013/A1

December 2017

ICS 11.040.25

English Version

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements - Amendment 1 (ISO 10555-1:2013/Amd 1:2017)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales - Amendement 1 (ISO 10555-1:2013/Amd 1:2017)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen - Änderung 1 (ISO 10555-1:2013/Amd 1:2017)

This amendment A1 modifies the European Standard EN ISO 10555-1:2013; it was approved by CEN on 15 December 2017.

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

Ref. No. EN ISO 10555-1:2013/A1:2017 E

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European foreword

This document (EN ISO 10555-1:2013/A1:2017) 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 10555-1:2013 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by December 2021.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, included in EN ISO 10555-1:2013.

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 10555-1:2013/A1:2017 has been approved by CEN as EN ISO 10555-1:2013/A1:2017 without any modification.

INTERNATIONAL STANDARD

ISO 10555-1

Second edition
2013-06-15

AMENDMENT 1
2017-11

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

AMENDMENT 1

Cathéters intravasculaires — Cathéters stériles et non réutilisables —
Partie 1: Exigences générales

AMENDEMENT 1

Reference number
ISO 10555-1:2013/Amd.1:2017(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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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.