ICS 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA Jún 2018

STN	**Intravaskulárne katétre Sterilné katétre a katétre na jednorazové použitie Časť 1: Všeobecné požiadavky (ISO 10555-1: 2013) Zmena A1**	**STN EN ISO 10555-1/A1** 85 5825

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2013, Corrected version 2013-07-01)

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. 05/18

Obsahuje: EN ISO 10555-1:2013/A1:2017, ISO 10555-1:2013/Amd 1:2017

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 10555-1:2013/A1

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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.

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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

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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of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by December 2021.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

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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

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Foreword

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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.