ICS 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA Február 2020

STN	**Intravaskulárne katétre Sterilné katétre a katétre na jednorazové použitie Časť 6: Podkožné implantované porty (ISO 10555-6: 2015/Amd 1: 2019) Zmena A1**	**STN EN ISO 10555-6/A1** 85 5825

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports (ISO 10555-6:2015)

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. 01/20

Obsahuje: EN ISO 10555-6:2017/A1:2019, ISO 10555-6:2015/Amd 1:2019

130118

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-6:2017/A1

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.

CEN members are the national standards bodies of 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 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

Ref. No. EN ISO 10555-6:2017/A1:2019 E

Contents

Page

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

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.

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

Cathéters intravasculaires — Cathéters stériles et non réutilisables —
Partie 6: Chambres à cathéter implantables
AMENDEMENT 1

Reference number
ISO 10555-6:2015/Amd.1:2019(E)

ISO 10555-6:2015/Amd.1:2019(E)

COPYRIGHT PROTECTED DOCUMENT

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
Website: 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).

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 www.iso.org/iso/foreword.html.

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.