



BSI Standards Publication

Intravascular catheters – Sterile and single-use catheters

Part 6: Subcutaneous implanted ports

National foreword

This British Standard is the UK implementation of EN ISO 10555-6:2017+A1:2019. It is identical to ISO 10555-6:2015, incorporating amendment 1:2019. It supersedes BS EN ISO 10555-6:2017, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/205, Non-active medical devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2019
Published by BSI Standards Limited 2019

ISBN 978 0 539 03811 8

ICS 11.040.25

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2015.

Amendments/corrigenda issued since publication

Date	Text affected
31 December 2017	This corrigendum renumbers BS ISO 10555-6:2015 as BS EN ISO 10555-6:2017
31 October 2019	Implementation of ISO amendment 1:2019 with CEN endorsement A1:2019

English Version

Intravascular catheters — Sterile and single-use catheters — Part 6: Subcutaneous implanted ports

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

Intravaskuläre Katheter — Sterile Katheter zur einmaligen Verwendung — Teil 6: Subkutan implantierte Ports

This European Standard was approved by CEN on 30 July 2017.

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, 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: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of ISO 10555-6:2015 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10555-6:2017 by 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 February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

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](#) which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of [Annex ZA](#)’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 10555-1:2013	EN ISO 10555-1:2013	ISO 10555-1:2013
ISO 10555-3:2013	EN ISO 10555-3:2013	ISO 10555-3:2013

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 10555-6:2015 has been approved by CEN as EN ISO 10555-6:2017 without any modification.

Foreword to amendment A1

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.

Contents

Page

Foreword	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements of the implantable subcutaneous implanted port and catheter	3
4.1 General.....	3
4.2 Biocompatibility.....	4
4.3 Distance markings.....	4
4.4 Nominal dimensions of the subcutaneous implanted port.....	4
4.5 Physical requirements.....	4
4.5.1 Radio-detectability.....	4
4.5.2 Surface finish.....	4
4.5.3 Freedom from leakage.....	4
4.5.4 Flushing volume.....	4
4.5.5 Characteristics of the septum.....	5
4.5.6 Characteristics of the connection or the catheter.....	5
4.6 Flow rate.....	5
4.6.1 Subcutaneous implanted ports not indicated for power injection.....	5
4.6.2 Subcutaneous implanted ports indicated for power injection.....	5
4.7 Burst pressure of the subcutaneous implanted port and catheter.....	6
4.7.1 Subcutaneous implanted ports not indicated for power injection.....	6
4.7.2 Subcutaneous implanted ports indicated for power injection.....	6
5 Magnetic Resonance Imaging (MRI) compatibility	6
6 Information to be supplied by the manufacturer	6
6.1 Marking on the device.....	6
6.2 Primary packaging.....	6
6.3 Labels for traceability.....	7
6.4 Instruction for use.....	7
Annex A (normative) Test method for freedom from air leakage	8
Annex B (informative) Determination of flushing volume	10
Annex C (informative) Guidance on further characterization testing: Needle penetration and withdrawal	12
Annex D (normative) Test method for freedom from leakage after multiple punctures	14
Annex E (normative) Peak tensile force	15
Bibliography	16

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 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 intravascular catheters*.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

- *Part 1: General requirements*
- *Part 3: Central venous catheters*
- *Part 4: Balloon dilatation catheters*
- *Part 5: Over-needle peripheral catheters*
- *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

- *Part 2: Angiographic catheters*

Intravascular catheters – Sterile and single-use catheters —

Part 6: Subcutaneous implanted ports

1 Scope

This part of ISO 10555 specifies requirements, performance, and user safety issues related to subcutaneous implanted ports and catheters for intravascular long-term use supplied in sterile condition and intended for single use.

This part of ISO 10555 does not specify requirements, performance, and user safety issues related to non-coring needles.

NOTE Subcutaneous implanted ports are known to be used for indications other than intravascular such as intra-peritoneal, intra-thecal, intra-pleural, and epidural access.

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 10555-1:2013, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

ISO 10555-3:2013, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10555-1 and the following apply.

3.1

catheter

single- or multiple-lumen tube allowing access to a point within the body at its distal end

3.2

connection

system connecting the catheter to the subcutaneous implanted port

3.3

effective surface area

area available for puncture by the needle

3.4

flushing volume

volume of solution needed to fully replace one solution from the subcutaneous implanted port and catheter with another