Irish Standard
I.S. EN ISO 10555-6:2017

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

I.S. EN ISO 10555-6:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 10555-6:2017 is the adopted Irish version of the European Document EN ISO 10555-6:2017, Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports (ISO 10555-6:2015)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-6

August 2017

ICS 11.040.25

English Version

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

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 6: Chambres à cathéter implantables (ISO 10555-6:2015)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 6: Subkutan implantierte Ports (ISO 10555-6:2015)

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

Ref. No. EN ISO 10555-6:2017 E

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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.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request M/295 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
7.5	4.2	ER 7.5 is covered only in respect of biocompatibility. Covers lubricants limited size drops on surfaces in design and manufacturing.
9.1	4.5.3, 4.5.6.1, 6.4 g)	ER 9.1 is covered by Standard Clause 4.5.3 in respect of leakage only. ER 9.1 is covered by Standard Clause 4.5.6.1 only in respect of peak tensile force between the port and the catheter. ER 9.1 is covered by Standard Clause 6.4g only in respect of specifications of the devices required to connect the port to the power injector. The connection must be standardized. The maximum for the connected injector. The intended purpose should be stated on the label

Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		or in the instruction for use, if not obvious. A pressure limit and maximum flowrate is required in the instruction for use, if the catheter is indicated for power injection. Covers restrictions on use indicated on labelling.
9.2	4.5.3, 4.5.4, 4.6, 4.7, 5	ER 9.2 first dash is covered by Standard Clause 4.5.3 in respect of leakage only. ER 9.2 first dash is covered by Standard Clause 4.5.4 in respect of the flushing volume only. ER 9.2 first dash is covered by Standard Clause 4.6 in respect of the flow rate only. ER 9.2 first dash is covered by Standard Clause 4.7 in respect of the burst pressure. ER 9.2 second dash is covered by Standard Clause 5 in respect of MRI compatibility only. The risk of injury, in connection with physical features including the volume/pressure ratio and dimensional features in the design process.
12.7.1	4.5.3, 4.6.2, 4.7.2	ER 12.7.1 is covered by Standard Clause 4.5.3 in respect of leakage only. ER 12.7.1 is covered by Standard Clause 4.6.2 in respect of flow rate only. ER 12.7.1 is covered by Standard Clause 4.7.2 in respect of burst pressure only. The catheter and port must be designed to protect the patient.
12.9	4.3	ER 12.9 is covered in respect of distance marking on the catheter only. Indicators for length adjustment.
13.3 a)	6.3	Standard Clause 6.3 first dash covers ER 13.3 a) but only in respect of the name of the manufacturer and only provided the labels are located as required by the Directive.
13.3 b)	6.1, 6.3	Standard Clause 6.1 covers ER 13.3 b) only in respect of the marking on the actual product. Standard Clause 6.3 second and third dash covers ER 13.3 b) but only in respect of the designation and item number and Batch/Lot/serial number.
13.3 d)	6.3	ER 13.3 d) is covered by Standard Clause 6.3 third dash but only when the any batch code is preceded by the word 'LOT'. Label and traceability label
13.4	6.2, 6.4	ER 13.4 is covered by Standard Clause 6.2 but only in respect of identification of power injection.

Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		ER 13.4 is covered by Standard Clause 6.2 but only in respect of the information given in Standard Clause 6.4 a-g.
13.6 a)	6.4	
13.6 b)	6.4	Only covers devices for power injection.
13.6 c)	6.4 g)	
13.6 d)	6.4 c), d)	
13.6 e)	6.4 a)	
13.6 f)	6.4 e)	
13.6 i)	6.4 g)	
13.6 l)	6.4 e)	Precautions to be taken as regards exposure in reasonably foreseeable environmental conditions to magnetic fields.
13.6 n)	6.4	Does not specify 'unusual risk'.
13.6 q)	6.4	

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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INTERNATIONAL STANDARD

ISO 10555-6

First edition
2015-04-15

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

Reference number
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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).

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