Irish Standard
I.S. EN ISO 10555-5:2013

Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)

I.S. EN ISO 10555-5:2013

Incorporating amendments/corrigenda/National Annexes issued since publication:

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EUROPEAN STANDARD

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EN ISO 10555-5

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Supersedes EN ISO 10555-5:1997

English Version

Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 5: Cathéters périphériques à aiguille interne (ISO 10555-5:2013)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO 10555-5:2013)

This European Standard was approved by CEN on 29 May 2013.

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.

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Foreword

This document (EN ISO 10555-5:2013) has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” in collaboration with 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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10555-5:1997.

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.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10555-5:2013 has been approved by CEN as EN ISO 10555-5:2013 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC amended by Directive 2007/47/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, 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 relevant Essential Requirements of that Directive.

NOTE 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 Directive 93/42/EEC amended by Directive 2007/47/EEC

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 10555-5
7.3	4.1
7.5	4.1
8.1	4.1
8.3	4.1
8.4	4.1
9.1	4.1 4.3.3.3
9.2	4.1 4.2 4.3.3.2 4.3.3.3 4.3.3.4 4.3.4
12.7.1	4.1 4.3.3.2
12.7.4	4.1
12.8.1	4.1
12.9	4.2
13.1	4.1
13.2	4.1

13.3 a)	4.1
13.3 b)	4.1
13.3 c)	4.1
13.3 d)	4.1
13.3 e)	4.1
13.3 f)	4.1
13.3 i)	4.1
13.3 j)	4.1 4.4 a) and c)
13.3 k)	4.1 4.4 b)
13.3 m)	4.1
13.4	4.1
13.6 a)	4.1
13.6 b)	4.1
13.6 c)	4.1
13.6 e)	4.1
13.6 f)	4.1
13.6 g)	4.1
13.6 k)	4.1
13.6 l)	4.1
13.6 n)	4.1
13.6 q)	4.1

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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EN ISO 10555-5:2013

INTERNATIONAL STANDARD

ISO 10555-5

Second edition
2013-06-15

Intravascular catheters — Sterile and single-use catheters —

Part 5: Over-needle peripheral catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 5: Cathéters périphériques à aiguille interne

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10555-5 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-5:1996), which has been technically revised. It also incorporates the Amendment ISO 10555-5:1996/Amd 1:1999 and the Technical Corrigendum ISO 10555-5:1996/Cor 1:2002.

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*

The following part is under preparation:

— *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*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters, and to ISO 14972, which specifies requirements for sterile obturators for use with over-needle peripheral catheters.

Intravascular catheters — Sterile and single-use catheters —

Part 5: Over-needle peripheral catheters

1 Scope

This part of ISO 10555 specifies requirements for over-needle peripheral intravascular catheters, intended for accessing the peripheral vascular system, supplied in the sterile condition and intended for single use.

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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*[1)]

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

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

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
over-needle peripheral intravascular catheter
catheter designed for the introduction or withdrawal of liquids or devices into or from the peripheral vascular system

3.2
needle
assembly comprising at least a needle tube attached to, and communicating with, a needle hub

See Figure 1.

3.3
needle tube
rigid tube with one end sharpened to facilitate entry into body tissue

3.4
needle hub
fitting attached to the needle tube, providing communication with its bore

3.5
vent fitting
fixed or removable fitting permitting venting of air while restricting or preferably preventing the escape of blood

1) Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.