BS EN ISO 10555-3:2013

BSI Standards Publication

Intravascular catheters — Sterile and single-use catheters

Part 3: Central venous catheters (ISO 10555-3:2013)

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National foreword

This British Standard is the UK implementation of EN ISO 10555-3:2013. It supersedes BS EN ISO 10555-3:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

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.

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

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EN ISO 10555-3

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English Version

Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters (ISO 10555-3:2013)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 3: Cathéters centraux veineux (ISO 10555-3:2013)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 3: Zentrale venöse Katheter (ISO 10555-3:2013)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 10555-3:2013: E

Foreword

This document (EN ISO 10555-3:2013) 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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.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 10555-3:1997.

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 10555-3:2013 has been approved by CEN as EN ISO 10555-3:2013 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 10555-3
7.3	4.1
7.5	4.1
8.1	4.1
8.3	4.1
8.4	4.1
9.1	4.1
9.2	4.1 4.2 4.3 4.4
12.7.1	4.1 4.4
12.7.4	4.1
12.8.1	4.1
12.9	4.2* 4.3*
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
13.3 k)	4.1 4.5 d)
13.3 m)	4.1
13.4	4.1
13.6 a)	4.1
13.6 b)	4.1 4.5 a), b) and c)
13.6 c)	4.1
13.6 e)	4.1
13.6 f)	4.1
13.6 g)	4.1
13.6 h	4.5 c)**
13.6 k)	4.1
13.6 l)	4.1
13.6 n)	4.1
13.6 q)	4.1
(*) Not applicable for the patient. **(**)** The information is on cleaning even though it is not a reusable devices.	

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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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.

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ISO 10555-3 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 10555-3:1996), which has been technically revised. It also incorporates the Technical Corrigendum ISO 10555-3:1996/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.

INTERNATIONAL STANDARD **ISO 10555-3:2013(E)**

Intravascular catheters — Sterile and single-use catheters —

Part 3: Central venous catheters

1 Scope

This part of ISO 10555 specifies requirements for central venous catheters 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 10555-1:2013, *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
central venous catheter
intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements

Note 1 to entry: The catheter can have a fixation system which is part of the device.

4 Requirements

4.1 General

Catheters shall comply with ISO 10555-1, except for the peak tensile force (see ISO 10555-1:2013, 4.6), for which the requirements of 4.4 of this part of ISO 10555 shall apply.

4.2 Distance markings

If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5 cm.

It is recommended that the distance marks be 1 cm apart on that portion of the catheter likely to be of importance to the user in positioning the catheter and monitoring catheter migration.

4.3 Lumen markings

For multilumen catheters, identification of each lumen shall be apparent to the user.

4.4 Peak tensile force

For catheters having a tip of softer durometer material or of different construction to the shaft and not exceeding 20 mm in length, the minimum peak tensile force of the tip shall be as given in Table 1 when tested in accordance with the method given in ISO 10555-1:2013, Annex B.

The minimum peak tensile force of all other parts of such catheters shall comply with ISO 10555-1:2013, 4.6.

Table 1 — Minimum peak tensile force of soft tips of length not exceeding 20 mm

Smallest outside diameter of catheter body mm	Minimum peak tensile force N
≥ 0,550 and < 0,75	3
≥ 0,75 and < 1,85	4
≥ 1,85	5

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also contain the following:

a) if the catheter is provided with distance markings, a description of the marking system;

b) flowrate for each lumen;

c) maximum guidewire diameter, where applicable;

d) if applicable, a warning against attempting to withdraw the catheter back through the needle;

e) at least one recommended cleaning agent.

Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

Bibliography

[1] ISO 11070, *Sterile, single-use intravascular catheter introducers*

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