BSI Standards Publication

Intravascular catheters - Sterile and single-use catheters

Part 1: General requirements

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 10555-1:2013+A1:2017. It is identical to ISO 10555-1:2013 +A1:2017, incorporating ISO corrected text January 2014.
It supersedes BS EN ISO 10555-1:2013, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment A1 is indicated by 〚A1〉 〈A1〛.

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.

Published by BSI Standards Limited 2018

ISBN 978 0 580 92760 7

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 31 July 2013.

Amendments/corrigenda issued since publication

Date	Text affected
30 April 2014	Implementation of ISO corrected text 15 January 2014 editorial correction in H.2 and H.3.
31 March 2018	Implementation of ISO amendment 1:2017 with CEN endorsement A1:2017

EUROPEAN STANDARD EN ISO 10555-1:2013

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2017

ICS 11.040.25

English Version

Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013, Corrected version 2013-07-01)

Cathéters intravasculaires — Cathéters stériles et non réutilisables — Partie 1: Exigences générales (ISO 10555-1:2013, Version corrigé 2013-07-01)

Intravaskuläre Katheter — Sterile Katheter zur einmaligen Verwendung — Teil 1: Allgemeine Anforderungen (ISO 10555-1:2013, korrigierte Fassung 2013-07-01)

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.

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, 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 10555-1:2013+A1:2017: E

European foreword

This document (EN ISO 10555-1:2013, Corrected version 2013-07-01) 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 10555-1:2009.

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 10555-1:2013, Corrected version 2013-07-01 has been approved by CEN as EN ISO 10555-1:2013 without any modification.

Foreword to amendment A1

This document (EN ISO 10555-1:2013/A1:2017) 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 10555-1:2013 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by December 2021.

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, included in EN ISO 10555-1:2013.

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 10555-1:2013/A1:2017 has been approved by CEN as EN ISO 10555-1:2013/A1:2017 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 10555-1
7.3	4.5* 4.9 4.10*
7.5	4.4*
8.1	4.1* 6.2 c) and d)*
8.3	4.1* 6.2 c) and d)*
8.4	4.1**** 6.2 d)*
9.1	4.8 4.9 4.10 6.3 b), c) and i)

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 10555-1
9.2	4.2 4.4 4.6 4.7 4.8 4.9 4.10 4.11 4.12 5
12.7.1**	4.4 4.6 4.7 4.9 4.10 4.11 4.12
12.7.4	4.9 4.10
12.8.1	4.9 4.10
13.1	6.1 6.2 a), b), f), g), h), i), j), k) 6.4
13.2	6.1
13.3 a)	6.2 a)
13.3 b)	6.2 b)
13.3 c)	6.2 c)
13.3 d)	6.2 e)
13.3 e)	6.2 f)
13.3 f)	6.2 g)
13.3 i)	6.2 h)
13.3 j)	6.2 i) and j) 6.3 c) and i)
13.3 k)	6.3 b) and f)
13.3 m)	6.2 d)
13.4	6.2 i) 6.3 a)
13.6 a)	6.3 a)***
13.6 b)	6.3 b)
13.6 c)	6.3 c) and f)
13.6 e)	6.3 f)

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 10555-1
13.6 f)	6.3 g)
13.6 g)	6.3 b) and f)
13.6 l)	6.3 b) and g)
13.6 n)	6.3 e)
13.6 q)	6.3 h)
(*) Not fully covered as the requirements are depended on the specific product. (**) For the user, only 4.7 is applicable. (***) Method of sterilisation not required in the instruction for use as it is required on the device or primary packing. (****) Only concerning sterilisation aspects.	

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

Contents

Page

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 10555-1 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 10555-1:1995), which has been technically revised. It also incorporates the amendments ISO 10555-1:1995/Amd 1:1999 and ISO 10555-1:1995/Amd 2:2004.

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.

This corrected version of ISO 10555-1:2013 incorporates an editorial correction in H.3.

Intravascular catheters - Sterile and single-use catheters —

Part 1:
General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

lt is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[2)]

ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes

3.2
distal end
end of the catheter inserted furthest into the patient

3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the cardiovascular system and the placement and anchoring of the distal tip in the chosen location

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

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