BRITISH STANDARD

BS EN ISO
10555-1:2009

Sterile, single-use intravascular catheters

Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)

ICS 11.040.25

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 10555-1:2009. It is identical to ISO 10555-1:1995, including amendment 1:1999 and amendment 2:2004. It supersedes BS EN ISO 10555-1:1997 which is withdrawn.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.

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

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EUROPEAN STANDARD

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English Version

Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)

Cathéters intravasculaires stériles, non réutilisables - Partie 1: Prescriptions générales (ISO 10555-1:1995, y compris Amd 1:1999 et Amd 2:2004)

Sterile intravaskuläre Katheter zur einmaligen Verwendung -Teil 1: Allgemeine Anforderungen (ISO 10555-1:1995, einschließlich Änderung 1:1999 und Änderung 2:2004)

This European Standard was approved by CEN on 19 April 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004 has been prepared by Technical Committee ISO/TC 84 “Medical devices for injections” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10555-1:2009 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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 10555-1:1996.

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 EC Directive.

For relationship with EC Directive, 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004 has been approved by CEN as a EN ISO 10555-1:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/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 the New Approach Directive 93/42/EEC on medical devices.

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

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive …	Qualifying remarks/Notes
4	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics
4.1	6, 7.2, 8.1	
4.2	6, 7.1, 7.5	"*E.R. 7.5 is only partially covered: protection against risks posed by the presence of phthalates and other toxic substances are not specifically addressed*"
4.4	6, 7.3	
4.6	6, 7.6	
4.7	9.1	
5	1, 3, 9.2	Except I 1. first indent – regarding ergonomics
6	3, 13.1, 13.4	
6 a)	13.3 b)	
6 d)	13.3 a)	except 13.3(a) (regarding representative in the Community)
6 e)	13.3 d)	
6 f)	13.3 e)	
6 g)	5	
6 h)	13.3 c)	
6 i)	13.3 m)	
6 j)	13.3 f)	Except 13.3 (f) (second phrase regarding indication of single use consistent across community)
6 k)	13.3 k)	
6 l)	7.3, 13.1, 13.3 i), 13.3 j), 13.3 k), 13.4, 13.6 a), 13.6 b), 13.6 g)	
Annex A	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics

Annex B	1, 2, 3, 4, 5	Except I 1. first indent – regarding ergonomics
Annex C	1, 2, 3, 4, 5, 7.6	Except I 1. first indent – regarding ergonomics
Annex D	1, 2, 3, 4, 5, 7.6	Except I 1. first indent – regarding ergonomics
NOTE	6a	Requirement on clinical evaluation not covered by this standard
NOTE	13.6 (h) – 2nd phrase	Regarding information on known characteristics and technical factors known to manufacturer that could pose a risk if reused is not covered by this standard
NOTE	13.6 (q)	regarding date of issue or latest revision of instructions for use is not covered by this standard

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

Sterile, single-use intravascular catheters —

Part 1:
General requirements

AMENDMENT 1

Page 1

Clause 3 Definitions

Delete existing definitions for 3.5 and 3.6, and substitute the following definitions:

3.5 effective length, *l*: Length of the catheter, or pre- and post-hydration lengths of hydratable catheters, that can be inserted into the body (see figure 1).

3.6 outside diameter: Maximum diameter of the catheter, or pre- and post-hydration maximum diameters of hydratable catheters, that can be inserted into the vessel.

Add the following new definitions:

3.8 hydratable intravascular catheter: Intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium.

3.9 post-hydration: State of a hydratable intravascular catheter after immersion in water at (37 ± 2) °C for 2 h.

3.10 clinically significant hydration: Hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 4 mm or 1 % of the effective length, whichever is the lesser, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more.

Page 3

Clause 4 Requirements

In the note in **table 1**, add the following text at the end of the sentence:

(pre-hydration outside diameter for hydratable intravascular catheters).

4.6.1 Add the following paragraph:

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.6.2 Add the following paragraph:

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

Add the following new subclause.

4.8 Flowrate

This part of ISO 10555 does not specify requirements for flowrate, but if the flowrate through hydratable catheters is determined, it shall be determined in both the pre- and post-hydration states.

Page 4

Clause 6 Information to be supplied by the manufacturer

Add the following text to items b) and c):

…, including pre- and post-hydration values for hydratable intravascular catheters.

Page 6

Clause B.1 Principle

Add the following new sentence at the end of B.1:

Hydratable catheters are tested in both the pre- and post-hydration states.

Subclause B.3.1 Add the following new paragraph:

For hydratable catheters, prepare identical test pieces from two catheters. Condition one test piece in accordance with B.3.2. Do not condition the other test piece; test it immediately in accordance with B.3.3 to B.3.8.

Subclause B.3.2 Delete the existing text and replace by the following:

Place the test pieces to be conditioned (see B.3.1) in distilled or deionized water at a temperature of (37 ± 2) °C for 2 h. Test in accordance with B.3.3 to B.3.8 immediately after conditioning.

Page 7

Clause C.4 Procedure

Add the following new subclause:

C.4.5 For hydratable intravascular catheters, carry out the steps in C.4.1 to C.4.4 on catheters in both the pre- and post-hydration states.

Clause C.5 Test report

Add the following text to item b):

(in both the pre- and post-hydration states for hydratable intravascular catheters).

Page 8

Clause D.4 Procedure

Add the following new subclause:

D.4.6 For hydratable intravascular catheters, carry out the steps in D.4.1 to D.4.5 on catheters in both the pre- and post-hydration states.

Clause D.5 Test report

Add the following text to item b):

(in both the pre- and post-hydration states for hydratable intravascular catheters).

Sterile, single-use intravascular catheters —

Part 1: General requirements

AMENDMENT 2

Page 1, *Clause 3*

Add the following definition:

3.11
coating
any material added to a catheter, in less than pharmacological concentrations, to modify the antithrombotic and/or antimicrobial properties of the catheter

NOTE The coating may be physically and/or chemically bonded to the surface, impregnated into the catheter surface or compounded as a constituent of the catheter material.

Page 4, Clause 6

Add the following items to the list:

m) duration of effectiveness in use of any specified coating(s) that have been applied;

n) if applicable, special claims made because of the presence of the coating;

o) if applicable, a description of the coating material;

p) if applicable, the method of coating addition, e.g.

- applied to the surface,
- impregnated into the surface,
- formulated or compounded as a component of the catheter material.

q) if applicable, known reactions between the catheter and magnetic resonance imaging (MRI);

r) if applicable, shelf life and storage conditions;

s) if applicable, any contra-indications, warnings and precautions based on the coating material(s.)

Contents

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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.

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.

International Standard ISO 10555-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

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

— *Part 1: General requirements*

— *Part 2: Angiographic catheters*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

Attention is drawn to ISO 11070, which will specify requirements for accessory devices for use with intravascular catheters.

Annexes A, B, C and D form an integral part of this part of ISO 10555. Annex E is for information only.

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INTERNATIONAL STANDARD © ISO **ISO 10555-1:1995(E)**

Sterile, single-use intravascular 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.

It does not apply to intravascular catheter accessories, which will be covered by a separate standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

3 Definitions

For the purposes of this part of ISO 10555, the following 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 proximal end; access end: End of the catheter to which connection can be made.

3.4 hub: Connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter.

3.5 effective length, *l*: Length of the catheter that can be inserted into the body. (See figure 1.)

3.6 outside diameter: Maximum diameter of that part of the catheter that can be inserted into the vessel.

3.7 junction: That portion of the catheter that joins one tube to multiple tubes.