BS EN ISO 10555-5:2013

BSI Standards Publication

Intravascular catheters — Sterile and single-use catheters

Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)

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National foreword

This British Standard is the UK implementation of EN ISO 10555-5:2013. It supersedes BS EN ISO 10555-5:1997 which is withdrawn.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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Amendments issued since publication

Date	Text affected

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English Version

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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.

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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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.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.

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Endorsement notice

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

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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

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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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Full document details: BS EN ISO 10555-5:2013

Contents

Page

Foreword ..... **iv**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Requirements **2**
4.1 General 2
4.2 Multilumen catheters 2
4.3 Physical requirements 3
4.4 Information to be supplied by the manufacturer 4
Annex A (normative) **Determination of strength of union of needle hub and needle tube** **5**
Annex B (informative) **Colours for opaque catheter hubs** **6**
Annex C (informative) **Needle point geometries** **7**
Annex D (normative) **Determination of liquid leakage from vent fitting** **8**
Bibliography **10**

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