

Sterile, single-use intravascular catheters —

Part 1: General requirements

The European Standard EN ISO 10555-1:1996, with the incorporation of amendments A1:1999 and A2:2004, has the status of a British Standard

ICS 11.040.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/27, Medical plastics tubing, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- British Dietetic Association (PENG)
- British Paediatric Association
- British Surgical Trades Association
- Department of Health
- Disposable Hypodermic and Allied Equipment Manufacturers Association (UK)
- Guild of Hospital Pharmacists
- Institution of Physics and Engineering in Medicine and Biology
- Intensive Care Society
- Medical Sterile Products Association
- National Association of Theatre Nurses
- Royal Pharmaceutical Society of Great Britain

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 January 1997

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Amendments issued since publication

Amd. No	Date	Comments
10805	January 2000	
15270	26 January 2006	See national foreword

The following BSI references relate to the work on this British Standard:
Committee reference CH/27
Draft for comment 91/53634 DC

ISBN 0 580 26384 3

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National foreword

This British Standard has been prepared by Technical Committee CH/27 and is the English language version of EN ISO 10555-1:1996 *Sterile, single-use intravascular catheters — Part 1: General requirements*, including amendments A1:1999 and A2:2004, published by the European Committee for Standardization (CEN).

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1**. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by **A1** **A1**.

It is identical with ISO 10555-1:1995, including amendment A1:1999 and A2:2004, published by the International Organization for Standardization (ISO).

BS EN ISO 10555-1:1996 supersedes BS 7174-1:1990 which is withdrawn.

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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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 13 and a back cover.

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ICS 11.040.20

Descriptors: Medical equipment, sterile equipment, disposable equipment, vascular system, catheters, specifications, tests, designation, consumer information

English version

Sterile, single-use intravascular catheters — Part 1: General requirements

(includes amendments A1:1999 + A2:2004)

(ISO 10555-1:1995 + A2:2004)

Cathéters, intravasculaires stériles, non
réutilisables —
Partie 1: Prescriptions générales
(inclut les amendements A1:1999 et A2:2004)
(ISO 10555-1:1995 + A2:2004)

Sterile intravaskuläre Katheter zur einmaligen
Verwendung —
Teil 1: Allgemeine Anforderungen
(enthält Änderungen A1:1999 und A2:2004)
(ISO 10555-1:1995 + A2:2004)

This European Standard was approved by CEN on 1996-07-08; amendment A1 was approved by CEN on 1999-06-25, amendment A2 was approved by CEN on 2004-05-03. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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CEN

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Comité Européen de Normalisation
Europäisches Komitee für Normung

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Ref. No. EN ISO 10555-1:1996 + A1:1999 + A2:2004 E



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Foreword

The text of the International Standard from Technical Committee ISO/TC 84, Medical devices for injections, of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 205, Non-active medical devices, the secretariat of which is held by BSI.

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 February 1997, and conflicting national standards shall be withdrawn at the latest by January 1998.

This European Standard 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 ZB, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

Foreword to amendment A1

The text of this amendment EN ISO 10555-1:1996/A1:1999 to the EN ISO 10555-1:1996 from Technical Committee ISO/TC 84, Medical devices for injections, of the International Organization for Standardization (ISO) has been taken over as an amendment to the European Standard by Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This amendment to the European Standard EN ISO 10555-1:1996 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.

This amendment to the European Standard EN ISO 10555-1:1996 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).

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Endorsement notice

The text of amendment to the International Standard ISO 10555-1:1996/Amendment 1:1999 has been approved by CEN as an amendment to the European Standard without any modification.

Foreword to amendment A2

This document (EN ISO 10555-1:1996/A2:2004) has been prepared by Technical Committee ISO/TC 84, Medical devices for injections, in collaboration with Technical Committee CEN/TC 205, Non-active medical devices, the Secretariat of which is held by BSI.

This European Standards shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2004, and conflicting national standards shall be withdrawn at the latest by November 2004.

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

Endorsement notice

The text of ISO 10555-1:1996 has been approved by CEN as EN ISO 10555-1:1996/A2:2004 without any modifications.