

Sterile urethral catheters for single use

The European Standard EN 1616:1997, including its amendment A1:1999, 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/1, Catheters, upon which the following bodies were represented:

- Association of British Health-care Industries
- Association of Continence Advisors
- British Association of Urological Surgeons
- British Rubber Manufacturers' Association Ltd.
- Medical Sterile Products Association

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 July 1997

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The following BSI references relate to the work on this standard:
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National foreword

This British Standard has been prepared by Technical Committee CH/1 and is the English language version of EN 1616 : 1997 *Sterile urethral catheters for single use*, published by the European Committee for Standardization (CEN).

It supersedes BS 1695 : Part 1 : 1990 and Part 2 : 1990, which are withdrawn.

Cross-references

Publication referred to	Corresponding British Standard
EN 556 : 1994	BS EN 556 : 1995 <i>Sterilization of medical devices — Requirements for terminally-sterilized devices to be labelled ‘Sterile’</i>
EN 980 : 1996	BS EN 980 : 1997 <i>Graphical symbols for use in the labelling of medical devices</i>
EN 1618 : 1997	BS EN 1618 : 1997 <i>Catheters other than intravascular catheters — Test methods for common properties</i>
EN 20594-1 : 1993	BS EN 20594-1 : 1994 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements</i>

The Technical Committee has reviewed the provisions of prEN 1041, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this British Standard.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 12, an inside back cover and a back cover.

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Sideline in this document indicates the most recent changes by amendment.

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Descriptors: medical equipment, disposable equipment, urinary tract catheters, specifications, dimensions, flow rates, tensile strength, junctions, safety, labelling

English version

Sterile urethral catheters for single use

(includes amendment A1:1999)

Sondes urinaires stériles non réutilisables
(inclut l'amendement A1:1999)

Sterile Harnblasenkatheter zur einmaligen
Verwendung
(enthält Änderung A1:1999)

This amendment A1 modifies the European Standard EN 1616 : 1997; it was approved by CEN on 13 February 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared 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 August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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.

Annexes A, B, C and D form normative parts of this European Standard. Annex E is for information.

Foreword to EN 1616 : 1997/A1 : 1999

This Amendment EN 1616 : 1997/A1 : 1999 to EN 1616 : 1997 has been prepared 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 1616 : 1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

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