BRITISH STANDARD

BS EN
12439:1999

Sterile rectal catheters for single use

The European Standard EN 12439:1998 has the status of a British Standard

ICS 11.040.20

National foreword

This British Standard is the English language version of EN 12439:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/27, Medical plastics tubing, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 4, an inside back cover and a back cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 April 1999

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EUROPEAN STANDARD
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EN 12439

October 1998

ICS 11.040.20

Descriptors: medical equipment, rectal catheters, disposable equipment, definitions, specifications, dimensions, designation, tensile strength, gas permeability, labelling, packing, storage

English version

Sterile rectal catheters for single use

Sondes rectales stériles non réutilisables

Sterile Rektalkatheter zur einmaligen Verwendung

This European Standard was approved by CEN on 2 October 1998.

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.

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CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 12439:1998 E

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 April 1999, and conflicting national standards shall be withdrawn at the latest by April 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.

The document is based on DIN 13273-4, *Catheters for medical use — Part 4: Single-use rectal catheters*.

Annex A is given for information only.

Contents

1 Scope

This European Standard specifies requirements for single-use rectal catheters intended to be inserted into the rectum of a patient, for emptying, rinsing or filling purposes.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. The normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

EN 556:1994 + A1:1998, *Sterilization of medical devices — Requirements for terminally-sterilized medical devices to be labelled "Sterile".*

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN 1618, *Catheters other than intravascular catheters — Test methods for common properties.*

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1

rectal catheter

medical device consisting of a catheter tube, which can be fitted with a connector with tapered bore, intended to be inserted into the rectum of a patient

3.2

collapse

flattening of the shaft, obstructing the flow through the catheter

4 Requirements

4.1 General

The tests to ascertain that requirements are fulfilled shall be performed on the product in the ready-for-use state.

4.2 Dimensions and designation

Rectal catheter dimensions should be defined as designated in Figure 1.

The area of any eye shall not exceed the cross-sectional area of the lumen, and the tip shall be rounded and closed.

NOTE The design of the catheter in Figure 1 is an example and is given for information only. The size and position of the catheter eyes should not compromise the stiffness required for catheter insertion.

4.3 Biocompatibility

The catheter shall be evaluated for biocompatibility, and shall be free from biological hazard.

NOTE Methods for evaluation for biocompatibility are given in EN 30993.

4.4 Kink stability

NOTE This clause will be prepared when a test method has been developed.

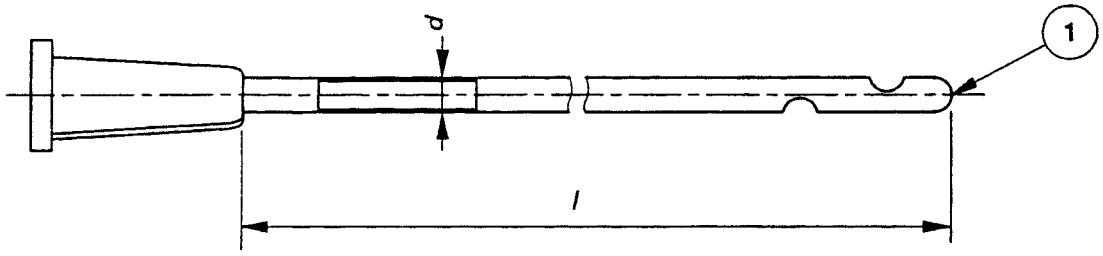
4.5 Surface

When the catheter is ready for use (i.e. treated according to the manufacturer's instructions) and is examined by normal or corrected-to-normal vision, the surface of the shaft, tip, and eyes shall appear free from extraneous matter.

The shaft and any openings in the tip shall be designed so as to minimize the risk of serious injury to mucous membranes.

4.6 Tensile properties

When tested as described in annex B of EN 1618, the catheter shall not break and the catheter and connector shall not become separated at an applied force of 15 N or less.



l = effective length
d = outer diameter

1 Closed, rounded tip

Figure 1 — Designation of dimensions

4.7 Collapse

4.7.1 When tested as described in **4.7.2**, the catheter shall not collapse.

4.7.2 Place the catheter, with its eyes blocked, in a water bath at a temperature of (37 ± 2) °C and keep it in the bath until temperature equilibrium has been reached. Apply a pressure of -10 kPa to the catheter for a period of 15 s. Examine the catheter for signs of collapse.

4.8 Air leakage

When tested as described in annex C of EN 1618 at a test pressure of 10 kPa, the joint between the catheter and the connector shall not leak.

4.9 Sterility

The catheter shall comply with EN 556:1994 + A1:1998.

5 Labelling

In addition to the requirements of EN 1041, the following product-specific details shall be presented on the individual packaging:

a) outer diameter, in millimetres, as designated in Figure 1;

b) effective length, in millimetres, as designated in Figure 1;

c) if the product contains latex, it shall be labelled to that effect.

NOTE Other units of measurement can be used in addition to the SI units specified in **5**a and **5**b.

Annex A (informative)
Bibliography

EN 30993, *Biological evaluation of medical devices.*

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