

Suction catheters for use in the respiratory tract

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British Standard

ICS 11.040.20

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Summary of pages

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English version

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Absaugkatheter zur Verwendung im Atemtrakt

This European Standard was approved by CEN on 5 July 1997.

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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 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI.

This European Standard is based on ISO 8836:1988 *Suction catheters for use in the respiratory tract*, prepared by ISO/TC 121. However, it differs from ISO 8836 in that it introduces a table of colour identification for use with suction catheters. It no longer includes requirements for suction catheters made of rubber, and the size should be designated by outside diameter expressed in millimetres.

Annexes A, B and C are normative and form part of this European Standard. Annexes D and E are for information only.

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of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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.

Contents

	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	3
4 Size designation and dimensions	4
5 Materials	5
6 Design	5
7 Performance requirements	5
8 Requirements for suction catheters supplied sterile	6
9 Marking	6
Annex A (normative) Test method for security of fit of female ends	8
Annex B (normative) Test method for security of construction	9
Annex C (normative) Test method for residual vacuum	9
Annex D (informative) Guidance on design and materials	10
Annex E (informative) Bibliography	10

Introduction

This European Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see prEN 1782 for details of tracheal tube standards and EN 1282-1 and EN 1282-2 for details of tracheostomy tube standards). Requirements for suction catheters made of rubber have been deleted because such catheters are no longer in general use.

Flammability of suction catheters, for example if flammable anaesthetics or lasers are used, is a well-recognized hazard that is addressed by appropriate clinical management, and is outside the scope of this standard.

1 Scope

This European Standard specifies requirements for suction catheters made of plastics materials and intended for use in suction of the respiratory tract. Specialized suction catheters are excluded from the scope of this standard. Angled tip suction catheters (e.g. Coudé catheters) are not considered to be specialized and are therefore included in the scope.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These 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, *Sterilization of medical devices — Requirements for medical devices to be labelled “STERILE”*.

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods*.

EN 30993-1, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests*.
(ISO 10993-1:1992 + Technical Corrigendum 1:1992)

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying requirements*.

3 Definitions

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

3.1

adaptor

specialized connector to establish functional continuity between otherwise disparate or incompatible components

3.2

connector

fitting to join together two or more components
[EN ISO 4135:1996]

3.3

effective shaft length

the main part of the catheter which is of uniform outside diameter

3.4

eye

lateral aperture near the patient end of the catheter
[EN ISO 4135:1996]

3.5

machine end

that end of the catheter which is intended to be connected to a source of vacuum [EN ISO 4135:1996]

3.6

patient end

that end of the catheter which is intended to be inserted into the patient [EN ISO 4135:1996]

3.7

residual vacuum

the negative pressure at the patient end of the suction catheter when the vacuum control device is in the relief position

3.8

suction catheter

flexible tube designed for introduction into a respiratory tract to remove material by suction
[EN ISO 4135:1996]

3.9

tip

extremity of the patient end of a catheter
[EN ISO 4135:1996]

3.10

vacuum control device

means provided at the machine end of a catheter to control the flow of air and entrained material
[EN ISO 4135:1996]

3.11

terminal orifice

central opening of the patient end of the suction catheter