

Anaesthetic and respiratory equipment — Tracheostomy tubes

Part 1. Tubes for use in adults

The European Standard EN 1282-1 : 1996 has the status of a
British Standard

ICS 11.040.10

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/45, Tracheal tubes and related equipment, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- British Paediatric Association
- British Surgical Trades Association
- Department of Health
- Medical Sterile Products Association
- National Association of Theatre Nurses

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National foreword

This British Standard has been prepared by Technical Committee CH/45 and is the English language version of EN 1282-1 : 1996 *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes for use in adults* published by the European Committee for Standardization (CEN). It supersedes BS 6149 : Part 1 : 1987 and BS 6149 : Part 2 : 1993, which are withdrawn.

BS 6149 was originally published in two parts, Part 1 covering connectors and Part 2 covering tracheostomy tubes for use in adults. This revision will also comprise two Parts, Part 1 covering tubes for use in adults and Part 2 covering tubes for paediatric use, each Part incorporating specifications for the relevant connectors. EN 1282-2, for paediatric tubes, is in preparation and, when published, will be implemented as BS EN 1282-2.

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 20594-1 : 1993	BS EN 20594 <i>Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment</i> Part 1 : 1994 <i>General requirements</i>
EN 30993-1 : 1993	BS EN 30993 <i>Biological evaluation of medical devices</i> Part 1 : 1994 <i>Guidance on selection of tests</i>

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, an EN title page, pages 2 to 12, an inside back cover and a back cover.

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Descriptors: medical equipment, anaesthetic equipment, artificial breathing apparatus, tracheostomy tubes, plastic tubes, rubber tubes, specifications, dimensions, designation, design, tests, marking, packing, labelling

English version

Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes for use in adults

Matériel respiratoire et d'anesthésie — Tubes de
trachéostomie — Partie 1: Tubes pour adultes

Anästhesie- und Beatmungsgeräte —
Tracheotomietuben — Teil 1: Tuben zur Anwendung
bei Erwachsenen

This European Standard was approved by CEN on 1996-10-04. 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

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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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard is based on ISO 5366-1 : 1986, *Tracheostomy tubes — Part 1: Connectors*, and ISO 5366-2 : 1985 *Tracheostomy tubes — Part 2: Basic requirements*. It is one of two parts dealing with tracheostomy tubes and connectors. EN 1282-2 specifies requirements for paediatric tracheostomy tubes made of plastics materials and/or rubber.

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 Directives, see informative annex ZA, which is an integral part of this standard.

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

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.

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