

Tracheostomy tubes

Part 2. Paediatric tubes

The European Standard EN 1282-2 : 1997 has the status of a British Standard

ICS 11.040.10

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

BSI
Documents



Document Sharing Hub

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
- Royal College of Paediatrics and Child Health

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

© BSI 1997

Amendments issued since publication

Amd. No.	Date	Text affected

The following BSI references relate to the work on this standard:
Committee reference CH/45
Draft for comment 93/505405 DC

ISBN 0 580 27916 2

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Text of EN 1282-2	3

National foreword

This British Standard has been prepared by Technical Committee CH/45 and is the English language version of EN 1282-2 *Tracheostomy tubes — Part 2 : Paediatric tubes*, published by the European Committee for Standardization (CEN).

Attention is drawn to BS EN 1282-1 : 1997, which gives requirements for tracheostomy tubes for use with adults, which supersedes BS 6149 : Part 1 : 1987 and Part 2 : 1993.

Cross-references

Publication referred to	Corresponding British Standard
EN 556	BS EN 556 : 1995 <i>Sterilization of medical devices. Requirements for terminally-sterilized devices to be labelled 'Sterile'</i>
EN 980	BS EN 980 : 1997 <i>Graphical symbols for use in the labelling of medical devices</i>
prEN 1281-1	BS EN 1281-1 <i>Anaesthetic and respiratory equipment. Conical connectors</i> Part 1 : 1997 <i>Cones and sockets</i>
EN 1282-1 : 1996	BS EN 1282 <i>Tracheostomy tubes</i> Part 1 : 1997 <i>Tubes for use with adults</i>
EN 20594-1	BS EN 20594 <i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment</i> Part 1 : 1994 <i>General requirements</i>
EN 30993-1	BS EN 30993 <i>Biological evaluation of medical devices</i> Part 1 : 1994 <i>Guidance on selection of tests</i>

The Technical Committee has reviewed the provisions of prEN 868-1 and prEN 1782 to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this British Standard.

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.

ICS 11.040.10

Descriptors: Medical equipment, anaesthetic equipment, artificial breathing apparatus, babies, children, tracheostomy tubes, plastic tubes, rubber hoses, dimensions, designation, design, tests, packing, marking

English version

Tracheostomy tubes — Part 2: Paediatric tubes

Tubes de trachéostomie —
Partie 2: Tubes pédiatriques

Tracheotomietuben —
Teil 2: Pädiatrische Tuben

This European Standard was approved by CEN on 1997-01-27. 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

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

© 1997 Copyright reserved to CEN members

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 August 1997, and conflicting national standards shall be withdrawn at the latest by June 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 ZA, 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.

This European Standard applies to tracheostomy tubes and has been prepared in two Parts. This Part addresses tubes for paediatric use; Part 1 specifies requirements for tracheostomy tubes with an inside diameter of 6,5 mm or greater for adult use. This Part of this European Standard differs from Part 1 in that it does not require the connector to be permanently attached to the tube.

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

Contents

	Page
Foreword	2
Introduction	3
1 Scope	3
2 Normative references	3
3 Definitions	4
4 Size designation and dimensions	4
5 Materials	4
6 Design and finish	4
7 Requirements for tracheostomy tubes supplied sterile	6
8 Marking	6
Annexes	
A (normative) Method for the security of attachment of permanently attached connector, if provided, and neck-plate to tracheostomy tube	8
B (normative) Method for determining the resting diameter of the cuff	8
C (informative) Guidance on materials and design	8
D (informative) Bibliography	9
ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	10