

DIN EN 1282-2:2009-12 (E)

Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified) (includes Amendment A1:2009)

Contents	Page
Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Size designation and dimensions	6
4.1 Designation of size of tube	6
4.2 Outside diameter	6
4.3 Length	7
4.4 Angle	8
5 Materials	8
6 Design and finish	8
6.1 Machine end	8
6.2 Paediatric tracheostomy tube connector	8
6.3 Inner tube	9
6.4 Neck-plate	10
6.5 Cuff	10
6.6 Inflating tubes for cuffs	10
6.7 Patient end	10
6.8 Introducer	10
7 Requirements for tracheostomy tubes supplied sterile	11
7.1 Sterility assurance	11
7.2 Packaging for tracheostomy tubes supplied sterile	11
8 Marking	11
8.1 Marking of tracheostomy tube	11
8.2 Marking of tracheostomy tube connectors	11
8.3 Marking of unit packs	11
9 Adaptor	13
Annex A (normative) Test for security of attachment of permanently attached connector, if provided, and neck-plate to tracheostomy tube	14
A.1 Principle	14
A.2 Apparatus	14
A.3 Procedure	14
A.4 Expression of results	15
Annex B (normative) Test method for determining the resting diameter of the cuff	16
B.1 Principle	16
B.2 Apparatus	16

B.3	Procedure	16
B.4	Expression of results	16
Annex C (informative) Guidance on materials and design		17
C.1	Materials	17
C.2	Design	17
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices		18
Bibliography		20