

# ILNAS

Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN ISO 5366-1:2004

### **Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)**

Matériel d'anesthésie et de réanimation  
respiratoire - Tube de trachéostomie -  
Partie 1: Tubes et raccords pour adultes  
(ISO 5366-1:2000)

Anästhesie- und Beatmungsgeräte -  
Tracheotomietuben - Teil 1: Tuben und  
Verbindungsstücke zur Anwendung bei  
Erwachsenen (ISO 5366-1:2000)

07/2004



## National Foreword

This European Standard EN ISO 5366-1:2004 was adopted as Luxembourgish Standard ILNAS-EN ISO 5366-1:2004.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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ILNAS-EN ISO 5366-1:2004

EUROPEAN STANDARD **EN ISO 5366-1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2004

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Supersedes EN 1282-1:1996

English version

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Teil 1: Tuben und Verbindungsstücke zur Anwendugn bei  
Erwachsenen (ISO 5366-1:2000, korrigiert und neu  
gedruckt im Jahre 2001)

This European Standard was approved by CEN on 21 June 2004.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

The text of ISO 5366-1:2000 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 5366-1:2004 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 January 2005, and conflicting national standards shall be withdrawn at the latest by January 2005.

This document supersedes EN 1282-1:1996.

This document 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 ZB, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

### Endorsement notice

The text of ISO 5366-1:2000 has been approved by CEN as EN ISO 5366-1:2004 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

## Annex ZA (normative)

### Normative references to international publications with their relevant European publications

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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements	EN 20594-1	1993
ISO 4135	2001	Anaesthetic and respiratory equipment - Vocabulary	EN ISO 4135	2001
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997

**Annex ZB**

(informative)

**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC**

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**WARNING:** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

**TABLE ZB.1 - Correspondence between this European Standard and EU Directives**

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
1	N/A	
2	N/A	
3	N/A	
4	1, 2 a), 3	
5	1, 2 a), 3, 7.1 a), 7.1 b), 7.2	
6	1, 2, 3, 9.2 a)	
6.1	4, 9.1, 9.3	
6.1.1	7.5	
6.1.4	7.5	
6.2	4	
6.3	9.1, 9.3	
6.4.1	4	
6.4.2	4	
6.5.2.1	2 b)	
6.5.3	9.1	
6.7	4	
7.1	8.1, 8.3, 8.4	