SLOVENSKI STANDARD
SIST EN ISO 7376:2004

01-februar-2004

Nadomeģ a:
SIST EN 1819:2000

Anestezijska in dihalna oprema - Laringoskopi za trahealno intubacijo (ISO 7376:2003)

Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2003)

Anästhesie- und Beatmungsgeräte - Laryngoskope für Trachealintubation (ISO 7376:2003)

Matériel d'anesthésie et de réanimation respiratoire - Laryngoscopes pour intubation trachéale (ISO 7376:2003)

Ta slovenski standard je istoveten z: **EN ISO 7376:2003**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 7376:2004 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7376

December 2003

ICS 11.040.55

Supersedes EN 1819:1997

English version

Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2003)

Matériel d'anesthésie et de réanimation respiratoire - Laryngoscopes pour intubation trachéale (ISO 7376:2003)

Anästhesie- und Beatmungsgeräte - Laryngoskope für Trachealintubation (ISO 7376:2003)

This European Standard was approved by CEN on 2 December 2003.

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 Management Centre 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 Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN ISO 7376:2003) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 June 2004, and conflicting national standards shall be withdrawn at the latest by June 2004.

This document supersedes EN 1819:1997.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7376:2003 has been approved by CEN as EN ISO 7376:2003 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.

Publication	Year	Title	EN	Year
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	Comments
4.1	1, 2, 12.9	
4.2.1	1, 2, 7.1, 7.3	
4.2.2	1, 2, 9.2	As per CEN
4.2.3	1, 2, 7.1, 7.3, 9.2	
4.2.4	1, 2	
4.3	4, 5, 7.1, 7.2, 8.6, 9.2,	
4.3.a	4, 5, 7.2	
4.3.b	4, 5, 7.2	
4.3.c	4, 5, 7.2	
4.4	2, 12.7.4, 12.8.2	
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5.2.1.2	3, 9.2	
5.2.2.1	3, 12.7.4	
5.2.2.2	3, 12.7.4	
5.2.2.3	3, 12.7.4	
5.2.2.4	3, 12.7.4	
5.2.3	3, 12.7.4	
5.3.1	2, 3	
5.3.2	2, 3	

5.3.3	2, 3	
5.4	3, 12.7.1	
5.5.1	3, 12.7.1	
5.5.2	3, 12.7.1	
5.6	3, 12.7.1	
6.1.1	3, 12.7.4	
6.1.2	3, 9.2	
6.1.3	3, 12.7.4	
6.1.4	7.5, 7.6	
6.1.5	3, 12.7.4	
6.2.1	2	
6.2.2	2	
7.1	2	
7.2	2, 3, 12.7.4	
8.1.1	3, 12.7.1	
8.1.2	2, 3, 12.7.1	
8.1.3	3, 12.7.4	
8.1.4	7.1	
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8.2.2	2, 12.7.1	
9.1	1, 8.1, 13.6(h)	
9.2	2, 8.1, 13.6(h)	
10.1	13.1, 13.3(a), 13.6(a)	
10.2	13.1, 13.3(a)	
10.3 a	13.1, 13.3(b)	
10.3 b	13.1, 13.3(b)	
10.3 c	2, 3	
10.3 d	2, 3, 12.9, 13.3(b)	
10.3 e	2, 13.2	
10.4	2, 13.5	
10.5	2, 13.2	
10.6 a	13.3(d), 13.5	
10.6 b	3, 8.3, 8.4, 8.7, 13.3 (c)	
10.6 c	8.3, 8.7, 13.1, 13.3(f)	
11	2, 13.1, 13.2, 13.3(i, j, k), 13.6(b)	
11 a)	13.6(d)	
11 b)	3, 8.1, 13.3(m), 13.6(h, i)	
11 c)	2, 6, 13.6(h)	

11 d)	13.6(g, i)	
11 e)	12.2, 12.6(d)	
11 f)	3, 12.2, 12.3	
11 g)	7.5	
11 h)	2, 13.3(j, k), 13.4, 13.6(h)	
11 i)	4, 9.2, 13.6(f)	
11 j)	4, 5, 13.3(c, f), 13.6(d, h)	
11 k)	4, 13.6(d)	
11 l)	2, 6, 12.7.5	
A	1,2,7.1, 12.7.1	
B	13.1	
C		
Annex ZB		Bibliography

INTERNATIONAL STANDARD

ISO 7376

First edition
2003-12-15

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

Matériel d'anesthésie et de réanimation respiratoire — Laryngoscopes pour intubation trachéale

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