SLOVENSKI STANDARD
SIST EN ISO 7376:2009

01-julij-2009

Nadomeġļa:
SIST EN ISO 7376:2004

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 7376:2009**

ICS:

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

SIST EN ISO 7376:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7376

April 2009

ICS 11.040.55

Supersedes EN ISO 7376:2003

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 21 March 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 7376:2003 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 7376:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7376:2003.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7376:2003 has been approved by CEN as a EN ISO 7376:2009 without any modification.

Annex ZA
(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 on medical devices.

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 clauses of this standard given in Table ZA.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.

Table ZA.1 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1	1 (first paragraph), 2, 12.9	
4.2.1	1 (first paragraph), 2, 7.1, 7.3	
4.2.2	1 (first paragraph), 2, 9.2	As per CEN
4.2.3	1 (first paragraph), 2, 7.1, 7.3, 9.2	
4.2.4	1 (first paragraph), 2	
4.3	4, 5, 7.1, 7.2, 8.6, 9.2	
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4.3.b	4, 5, 7.2	
4.3.c	4, 5, 7.2	
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5.1	1 (first paragraph), 2, 3, 9.2	
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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	
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5.3.3	2, 3	
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5.5.1	3, 12.7.1	
5.5.2	3, 12.7.1	

5.6	3, 12.7.1	
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8.1.2	2, 3, 12.7.1	
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8.1.4	7.1	
8.2.1	2, 12.7.1	
8.2.2	2, 12.7.1	
9.1	1 (first paragraph), 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)	
-	1 (first paragraph and 2nd paragraph, 1st dash)	This relevant Essential Requirement is not addressed in this European Standard
-	1 (first paragraph and 2nd paragraph, 2nd dash)	This relevant Essential Requirement is not addressed in this European Standard
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	7.1 (3rd dash)	This part of this Essential Requirement is not addressed in this European Standard
10.2	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
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)	
10.6 c)	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
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)	
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11 d)	13.6(g, i)	
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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	
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Annex ZB		Bibliography

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

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

Reference number
ISO 7376:2003(E)

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