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Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)

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English Version

Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)

Matériel d'anesthésie et de réanimation respiratoire - Laryngoscopes pour intubation trachéale (ISO 7376:2009)

Anästhesie- und Beatmungsgeräte - Laryngoskope für Trachealintubation (ISO 7376:2009)

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Foreword

This document (EN ISO 7376:2009) 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of an identical text or by endorsement, at the latest by February 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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 7376:2009, April.

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.

For relationship with EU 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 7376:2009 has been approved by CEN as a EN ISO 7376:2009 without any modification.

Annex ZA
(informative)

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

This International 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 Union 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 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 International Standard and Directive 93/42/EEC

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Clause(s)/subclause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
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10.2	13.3 (a)	The ER is not fully addressed.
10.3	13.1, 13.3 (b ,c, f)	
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10.6	13.3 (c, d, f), 13.5	ER 13.3 (f) is only partly addressed.
11 a)	13.6 (q)	
11 b)	13.6 (c)	
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11 e)	13.6 (d)	
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11 i)	6, 13.6 (h)	ER 6 (a) is not addressed.
11 j)	13.1, 13.3 (k), 13.6 (l)	
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WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this International standard.

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INTERNATIONAL STANDARD

ISO 7376

Second edition
2009-08-15

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

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

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 7376 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This second edition cancels and replaces the first edition (ISO 7376:2003), which has been technically revised.

Introduction

This International Standard gives requirements for laryngoscopes in tracheal intubation, hereinafter referred to as laryngoscopes, during anaesthesia, intensive care, emergency care and similar procedures, including requirements for reusable and single-use laryngoscope blades and handles.

Laryngoscopes are manufactured in several forms and can, for example, be of single-piece handle and blade construction or have a detachable blade and handle. In the latter case, the light source for illuminating the larynx during use is either a lamp attached to a blade or a lamp in the handle with a light guide in the blade. The minimum illumination from the laryngoscope is defined/disclosed.

The dimensions of laryngoscope blades are defined and disclosed to allow an informed decision by the operator to select the most appropriate instrument for intubation. Annexes A and B describe test methods. While Annexes C and D give blade markings and designs respectively, Annex E presents a rationale for certain subclauses in the main body of the document.

Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation

1 Scope

This International Standard gives general requirements for laryngoscopes used for intubation, and specifies critical dimensions for the handle and lamp of hook-on type laryngoscopes. It also addresses the interchangeability of blades and handles.

It is applicable only to instruments with an internal battery-operated power source for illuminating the larynx, since electrical safety requirements can be more stringent for instruments connected to mains or external power packs.

It is not applicable to surgical instruments known by the same generic name, nor is it applicable to

— flexible laryngoscopes or laryngoscopes designed for surgery,

— laryngoscopes powered from mains electricity supply,

— laryngoscopes connected by light-transmitting cables to external light sources, or

— video laryngoscopes designed to work with an external video system.

NOTE Instruments connected by light guides to an external light source could be subject to other International Standards.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5864, *ISO inch screw threads — Allowances and tolerances*

ISO 10993-1*, Biological evaluation of medical devices — Part 1: Evaluation and testing*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

EN 1041, *Information supplied by the manufacturer with medical devices*