



# SLOVENSKI STANDARD SIST EN ISO 5364:2016

01-december-2016

Nadomešča:  
SIST EN ISO 5364:2011

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**Anestezijska in dihalna oprema - Ustno-žrelne (orofaringealne) dihalne cevke (ISO 5364:2016)**

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)

Anästhesie- und Beatmungsgeräte - Oropharyngealtuben (ISO 5364:2016)

Matériel d'anesthésie et de réanimation respiratoire - Canules oropharyngées (ISO 5364:2016)

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**Ta slovenski standard je istoveten z: EN ISO 5364:2016**

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**ICS:**

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

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EUROPEAN STANDARD

EN ISO 5364

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2016

ICS 11.040.10

Supersedes EN ISO 5364:2011

English Version

## Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO 5364:2016)

Matériel d'anesthésie et de réanimation respiratoire -  
Canules oropharyngées (ISO 5364:2016)

Anästhesie- und Beatmungsgeräte -  
Oropharyngealtuben (ISO 5364:2016)

This European Standard was approved by CEN on 15 July 2016.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## European foreword

This document (EN ISO 5364:2016) 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of an identical text or by endorsement, at the latest by March 2017, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 5364:2011.

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 ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard "within the meaning of Annex ZA", the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

**Table – Correlations between normative references and dated EN and ISO/IEC standards**

| Normative references as listed in<br>Clause 2 | Equivalent dated standard        |                                  |
|---|----------------------------------|----------------------------------|
|   | EN                               | ISO/IEC                          |
| ISO 4135                                      | EN ISO 4135:2001                 | ISO 4135:2001                    |
| ISO 7000                                      | —                                | ISO 7000:2014                    |
| ISO 10993-1                                   | EN ISO 10993-1:2009              | ISO 10993-1:2009                 |
| ISO 11607-1                                   | EN ISO 11607-1:2009 +<br>A1:2014 | ISO 11607-1:2006 + AMD<br>1:2014 |
| ISO 15223-1                                   | EN 15223-1:— <sup>1</sup>        | ISO 15223-1:2015 <sup>1</sup>    |

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|   |               |   |
|---|---------------|---|
| EN 556-1:2001   | EN 556-1:2001 | — |
| 1 The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult <a href="http://www.iso.org/iso/publications_and_e-products/databases.htm?=">http://www.iso.org/iso/publications_and_e-products/databases.htm?=.</a> |               |   |

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

**Endorsement notice**

The text of ISO 5364:2016 has been approved by CEN as EN ISO 5364:2016 without any modification.

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## 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 Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] / [M/295 concerning the development of European Standards related to medical devices] / [reference number and title of any other standardization request as relevant] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 160].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]**

| Essential Requirements of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Remarks/Notes   |
|---|------------------------------------|---|
| 7.1 (second indent)                           | 5<br>10.3.1 c)<br>10.4 C)          | Partly covered. There are no requirements for materials apart from a requirement to indicate the presence of natural rubber (latex), if applicable. |
| 8.1   | 8<br>9.1<br>9.2<br>9.2             | Covered on for packaging of sterile devices.  |
| 8.3   | 9.3                                | Partly addressed by 9.3 which mandates the requirements of ISO 11607-1 that the   |

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|                                |  |  |
|--------------------------------|--|--|
|                                |  | packaging is suitable to prevent contamination during transportation and use.  |
| 8.7                            | 9.1  | Partly covered. Marked sterile if appropriate  |
| 9.2 (first two indents)        | 4<br>6<br>7                                | Partly covered to address only the risk of injury in connection with their physical features by specifying sizing and marking conventions for the length and ID of the airway and by testing for collapse and patency. |
| 12.7.1                         | 6  | Partly covered with a requirement to limit sharp edges.  |
| 13.1                           | 9<br>10<br>11                              |  |
| 13.2                           | 10.3.3<br>10.3.4                           | Covered only for the use of identification colours.  |
| 13.3 b)                        | 10.3.1 a)<br>10.3.3<br>10.5 a)<br>10.5 b)  |  |
| 13.3 c)                        | 10.4 a)<br>10.5 e)                         |  |
| 13.3 d)                        | 10.5 d)                                    | To cover this ER fully, the batch number must be preceded by the word 'LOT'.   |
| 13.3 e)                        | 10.5 f)                                    | To cover this ER fully, the 'strong' recommendation to state the use by date is mandatory.   |
| 13.3 f)                        | 10.4 b)<br>10.5 f)                         | Only the first sentence is covered.  |
| 13.3 k)                        | 10.3.1 c)<br>10.4 b)<br>10.4 c)<br>10.5 f) | Limited to indications only of single use and the presence of natural rubber (latex).  |
| 13.3 m)                        | 10.5 e)                                    | To cover this ER fully, the recommendation to provide the method of sterilisation is mandatory (if applicable).  |
| 13.6 h) (first paragraph only) | 11.1                                       |  |



**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2** — Other Union legislation may be applicable to the products falling within the scope of this standard.

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INTERNATIONAL  
STANDARD

ISO  
5364

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equipment — Oropharyngeal airways**

*Matériel d'anesthésie et de réanimation respiratoire — Canules  
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