SLOVENSKI STANDARD
SIST EN ISO 11990:2018

01-december-2018

Nadomešča:
SIST EN ISO 11990-1:2015
SIST EN ISO 11990-2:2015

Laserji in laserska oprema - Ugotavljanje odpornosti sapničnih (endotrahealnih) tubusov in manšete proti laserskemu žarku (ISO 11990:2018)

Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtubusschaft und Trachealtubusmanschette (ISO 11990:2018)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux (ISO 11990:2018)

Ta slovenski standard je istoveten z: **EN ISO 11990:2018**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
31.260	Optoelektronika, laserska oprema	Optoelectronics. Laser equipment

SIST EN ISO 11990:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11990

October 2018

ICS 31.260; 11.040.10

Supersedes EN ISO 11990-1:2014, EN ISO 11990-2:2014

English Version

Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux (ISO 11990:2018)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtubusschaft und Trachealtubusmanschette (ISO 11990:2018)

This European Standard was approved by CEN on 5 August 2018.

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

CEN members are the national standards bodies of 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN ISO 11990:2018) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 123 “Lasers and photonics” the secretariat of which is held by DIN.

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 April 2019, and conflicting national standards shall be withdrawn at the latest by April 2019.

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

This document supersedes EN ISO 11990-1:2014 and EN ISO 11990-2:2014.

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 the relationship with EU Directive(s) 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, 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11990:2018 has been approved by CEN as EN ISO 11990:2018 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request 'M/023 concerning the development of European standards related to medical devices' 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 169].

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 Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this European Standard	Remarks/Notes
7.1 (first indent only)	This entire standard	These Essential Requirements (ERs) are partly covered. This standard is intended to provide a test method that will allow an evaluation of the risk of ignition of the shaft and cuff of a tracheal tube associated with its use with lasers during ear, nose and throat surgery as part of the risk assessment as set out in these essential requirements.
7.3 (first part only)	This entire standard	
9.3	This entire standard	

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 product(s) falling within the scope of this standard.

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 an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

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

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	**ISO**
ISO 11146-1	EN ISO 11146-1:2005	ISO 11146-1:2005
ISO 11810	EN ISO 11810:2015	EN ISO 11810:2015
ISO/IEC Guide 99	—	ISO/IEC Guide 99:2007
ISO 5361:2016	EN ISO 5361:2016	ISO 5361:2016
ISO 11145:2016	EN ISO 11145:2016	ISO 11145:2016

INTERNATIONAL STANDARD

ISO 11990

Third edition
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Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs

Lasers et équipements associés aux lasers — Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux

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Contents

Page