BS EN ISO 11990-1:2014

BSI Standards Publication

Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes

Part 1: Tracheal tube shaft

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National foreword

This British Standard is the UK implementation of EN ISO 11990-1:2014. It is identical to ISO 11990-1:2011. It supersedes BS EN ISO 11990-1:2011 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CPW/172, Optics and Photonics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments issued since publication

Date	Text affected

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 11990-1:2011

English Version

Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 1: Tracheal tube shaft (ISO 11990-1:2011)

Lasers et équipements associés aux lasers - Détermination de la résistance au laser des tubes trachéaux - Partie 1: Axe des tubes trachéaux (ISO 11990-1:2011)

Laser und Laseranlagen - Bestimmung der Laserresistenz von Trachealtuben - Teil 1: Trachealtubusschaft (ISO 11990-1:2011)

This European Standard was approved by CEN on 22 October 2014.

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.

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Foreword

The text of ISO 11990-1:2011 has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11990-1:2014 by 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 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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 11990-1:2011.

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.

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, 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 11990-1:2011 has been approved by CEN as EN ISO 11990-1:2014 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 (Medical Devices)

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 Union 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.

NOTE 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 on Medical Devices

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

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

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Full document details: BS EN ISO 11990-1:2014

Contents

Page

Foreword iv
Introduction v
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Principle 2
5 Significance and use of the test 3
6 Apparatus 3
6.1 Gas supply system 3
6.2 Containment box 4
6.3 Smoke evacuation 5
6.4 Lasers and delivery systems 5
6.5 Oxygen analyser 6
7 Reagents and materials 6
8 Preparation of test specimen 6
9 Preparation of apparatus 6
10 Test procedure 7
11 Interpretation of results 8
12 Test report 8
Bibliography 10

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Documents
Document Sharing Hub
Full document details: BS EN ISO 11990-1:2014

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 11990-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This first edition of ISO 11990-1 cancels and replaces ISO 11990:2003, of which it constitutes a minor revision.

ISO 11990 consists of the following parts, under the general title *Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes*:

— *Part 1: Tracheal tube shaft*

— *Part 2: Tracheal tube cuffs*

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