

SLOVENSKI STANDARD

SIST EN ISO 11810:2016

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Nadomešča:

SIST EN ISO 11810-1:2009

SIST EN ISO 11810-2:2009

Laserji in z laserji povezana oprema - Preskusna metoda in klasifikacija za ugotavljanje odpornosti proti laserju za operacijska pokrivala in/ali za varovalna pokrivala za paciente - Primarno zgorevanje, prodiranje, širjenje plamena in sekundarno zgorevanje (ISO 11810:2015)

Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition, penetration, flame spread and secondary ignition (ISO 11810:2015)

Lasers und Laseranlagen - Prüfverfahren und Einstufung zur Laserresistenz von Operationstüchern und/oder anderen Abdeckungen zum Schutz des Patienten - Primäre Entzündung, Laserdurchstrahlung und sekundäre Entzündung (ISO 11810:2015)

Lasers et équipements associés aux lasers - Méthode d'essai et classification de la résistance au laser pour des draps chirurgicaux et/ou des couvertures de protection des patients - Inflammation principale, pénétration et inflammation secondaire (ISO 11810:2015)

Ta slovenski standard je istoveten z: EN ISO 11810:2015

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
13.340.99	Druga varovalna oprema	Other protective equipment
31.260	Optoelektronika, laserska oprema	Optoelectronics. Laser equipment

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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11810

December 2015

ICS 11.040.30; 13.340.99; 31.260

Supersedes EN ISO 11810-1:2009, EN ISO 11810-2:2009

English Version

Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition, penetration, flame spread and secondary ignition (ISO 11810:2015)

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This European Standard was approved by CEN on 24 October 2015.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 11810:2015) 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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 11810-2:2009, EN ISO 11810-1:2009.

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 11810:2015 has been approved by CEN as EN ISO 11810:2015 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 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
The 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 laser induced flammability and temperature increase associated with the use of a surgical drapes during laser surgery as part of the risk assessment as set out in these essential requirements.
The entire standard	9.3	
The entire standard	12.7.3	

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

INTERNATIONAL
STANDARDISO
11810Second edition
2015-12-15

**Lasers and laser-related equipment —
Test method and classification for the
laser resistance of surgical drapes
and/or patient protective covers —
Primary ignition, penetration, flame
spread and secondary ignition**

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*Lasers et équipements associés aux lasers — Méthode d'essai et
classification de la résistance au laser pour des draps chirurgicaux
et/ou des couvertures de protection des patients — Inflammation
principale, pénétration et inflammation secondaire*

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ISO 11810:2015(E)

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Electro-optical systems*.

This second edition cancels and replaces ISO 11810-1:2005 and ISO 11810-2:2007 which have been technically revised.

Introduction

Some laser applications in medicine can require laser-resistant surgical drapes or other patient-protective covers. Surgical drapes or other patient-protective covers are necessary when a sterile procedure is performed and the surrounding area needs to be protected from liquids, secretions and inadvertent laser radiation. While conventional surgical drapes or other patient-protective covers are not necessarily laser-resistant, specifically designed surgical drapes offer the possibility of laser resistance.

Laser induced risks include ignition, flammability, melting, penetration, thermal transfer and reflectivity. Textile and non-woven drape materials can have other risks but they can provide a laser barrier. While there are many potential ignition devices present in the operating room (e.g. fibre optic illumination systems, electro-surgical units, hot wire cauteries), this test method addresses only the laser ignition source. This International Standard is intended for use in testing a surgical drape or other patient-protective cover that claims to be laser-resistant. In addition, areas within this product can vary in material composition or design. Depending on the claims being made by the manufacturer or end-user requirements, all areas for which laser resistance is claimed might need to be tested.

CO₂ lasers can induce the most challenging conditions of all medical lasers. Ignition/flammability tests and penetration tests can reveal more challenging laser wavelengths as well as modes of laser delivery, for example Q-switching in the nanosecond range. The 20 W CO₂ laser (continuous wave) has been selected as the laser for this International Standard.

Users of this test method are cautioned that the laser resistance of a surgical drape or other patient-protective cover will be wavelength sensitive and that a surgical drape or other patient-protective cover should be tested at the wavelengths for which it is intended to be used. If tested using other wavelengths, it is necessary to explicitly state the power settings and modes of delivery.

The results from this International Standard should not be applied to other wavelengths and temporal formats.

The performance of laser-resistant surgical drapes or other patient-protective covers can be changed when used in combination rather than individually.

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