BS EN ISO 11810:2015

BSI Standards Publication

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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National foreword

This British Standard is the UK implementation of EN ISO 11810:2015. It supersedes BS EN ISO 11810-2:2009 and BS EN ISO 11810-1:2009 which are withdrawn.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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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)

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)

Laser 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)

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.

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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.

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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 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	12.7.5	

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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Document Sharing Hub
Full document details: BS EN ISO 11810:2015

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Principle ... **3**
5 Significance and use of the test ... **3**
6 Apparatus ... **4**
6.1 General ... 4
6.2 Containment box ... 5
6.3 Specimen holder ... 5
6.4 Laser system ... 9
6.4.1 Laser ... 9
6.4.2 Power meter ... 9
6.5 Gas supply system ... 9
6.6 Environment ... 9
6.6.1 Ambient air conditions ... 9
6.6.2 Oxygen enriched atmospheres ... 9
6.7 Smoke evacuation device ... 10
7 Reagents and materials ... **10**
8 Preparation of specimens ... **10**
8.1 Sampling ... 10
8.1.1 Single use products ... 10
8.1.2 Reusable products ... 10
8.2 Specimens ... 10
8.3 Quantities ... 10
8.4 Conditioning ... 10
9 Preparation of apparatus ... **11**
10 Test methods ... **11**
10.1 General conditions ... 11
10.2 Primary ignition and penetration ... 11
10.2.1 Principle ... 11
10.2.2 Testing procedure ... 14
10.3 Secondary ignition ... 15
10.3.1 Principle ... 15
10.3.2 Testing procedure ... 16
11 Classification ... **18**
11.1 General ... 18
11.2 Laser-induced primary ignition (I) ... 18
11.3 Resistance to laser penetration (P) ... 18
11.4 Laser-induced secondary ignition (SI) ... 18
12 Test report ... **19**
Bibliography ... **20**

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Document Sharing Hub
Full document details: BS EN ISO 11810:2015

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.

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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.

CO_2 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 CO_2 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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INTERNATIONAL STANDARD ISO 11810:2015(E)

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

CAUTION — This test method can involve hazardous materials, operations and equipment. This International Standard provides advice on minimizing some of the risks associated with its use but does not purport to address all such risks. It is the responsibility of the user of this International Standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This International Standard is applicable to disposable and reusable, as well as woven and non-woven materials used as surgical drapes and other patient-protective covers which claim to be laser-resistant. The purpose of this International Standard is to provide a standardized method for testing and classifying surgical drapes and other patient-protective covers with respect to laser-induced hazards. An appropriate classification system is given. It is not the purpose of this International Standard to serve as a general fire safety specification, and as such, this International Standard does not cover other sources of ignition.

All materials reflect portions of the beam and it is necessary for the user to decide whether specular reflectance can be a hazard. This measurement, however, is not covered in this International Standard.

The test procedure can be used to assess the laser induced flammability properties of non-laser-resistant items

NOTE Users of products tested by this method are cautioned that the laser resistance of a surgical drape and/or patient-protective cover will be wavelength sensitive and that a surgical drape and/or patient-protective cover are better tested at the wavelength 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.

2 Normative references

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

ISO 11145, *Optics and photonics — Lasers and laser-related equipment — Vocabulary and symbols*

ISO 11146-1, *Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams*

ISO 80000-4, *Quantities and units — Part 4: Mechanics*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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