Laserid ja laseritega seotud seadmestik. Laseriga kasutamiseks sobivad kirurgilised eesriided ja/või patsiendi kaitsekatted. Osa 2: Teisene süttimine

Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11810-2:2009 sisaldab Euroopa standardi EN ISO 11810-2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11810-2:2009 consists of the English text of the European standard EN ISO 11810-2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 04.03.2009.	Date of Availability of the European standard text 04.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.30, 13.340.99, 31.260

Võtmesõnad: medi, medicine, optical equipment, optical instruments, optics, patient protection, plant, protection coverings, protective devices, radiation protection, specification (approval), specifications, surgical drapes, surgical equipment, surgical instruments, testing

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11810-2

March 2009

ICS 13.340.99; 31.260; 11.040.30

Supersedes EN ISO 11810-2:2007

English Version

Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition (ISO 11810-2:2007)

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 - Partie 2: Inflammation secondaire (ISO 11810-2:2007)

Laser und Laseranlagen - Prüfverfahren und Einstufung zur Laserresistenz von Operationstüchern und/oder anderen Abdeckungen zum Schutz des Patienten - Teil 2: Sekundäre Entzündung (ISO 11810-2:2007)

This European Standard was approved by CEN on 26 January 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11810-2:2009: E

Foreword

The text of ISO 11810-2:2007 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11810-2:2009 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 September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 11810-2:2007.

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 EC Directive.

For relationship with EC 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11810-2:2007 has been approved by CEN as a EN ISO 11810-2:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC

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 Communities under that Directive and has been implemented as a national standard in at least one Member State, 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.

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 EU Directive 93/42/EEC	Qualifying remarks/Notes
The entire standard	§§ 1; 2; 3; 4; 7.1; 9.3; 12.7.5; 13.1	Only the test method and the classification system

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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Introduction

Some laser applications in medicine may 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 drapes offer the possibility of laser resistance.

Laser-induced risks include ignition, inflammability, melting, penetration, thermal transfer and reflectivity. Textile and non-woven drape materials may have other risks but they may 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, etc., this test method addresses only the laser ignition source. A surgical drape or other patient protective cover that claims to be laser-resistant must be tested according to this part of ISO 11810.

CO_2 lasers may provide the most challenging conditions of all medical lasers. Ignition/inflammability tests and penetration tests may disclose 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 to be used for this part of ISO 11810. For laser-induced secondary ignition of drapes and/or patient protective covers, the risk is dependent on spot size at a given power setting. In addition, areas within a given product may vary in material composition or design. Depending on the claims being made by the manufacturer or end-user requirements, all areas within the product may need to be tested.

This part of ISO 11810 applies to secondary ignition and is provided with information additional to ISO 11810-1 for testing and reporting test results. The purpose of secondary ignition is to simulate a situation where a surgical drape or other protective cover is placed over another material. A piece of cotton gauze is used to simulate this other material. This part of ISO 11810 determines whether ignition of the cotton gauze will ignite the surgical drape and/or patient protective cover and whether the surgical drape and/or patient protective cover will continue to burn once the burning cotton has been removed. The afterflame of the surgical drape and/or protective cover is also determined.

The performance of laser resistant surgical drapes or other patient covers may be degraded when used in combination rather than individually.

Lasers and laser-related equipment — Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers —

Part 2: Secondary ignition

1 Scope

This part of ISO 11810 is applicable to disposable and re-usable, as well as woven and non-woven materials used as surgical drapes and/or patient protective covers which claim to be laser-resistant.

The purpose of this part of ISO 11810 is to provide a standardized method for testing and classifying surgical drapes and/or patient protective covers with respect to laser-induced hazards. An appropriate classification system is given. It is not the purpose of this part of ISO 11810 to serve as a general fire safety specification. This part of ISO 11810 is limited to testing the secondary ignition of materials that are rated I1 or I2 from ISO 11810-1.

All materials reflect portions of the beam and it is necessary for the user to decide whether specular reflection may be a hazard. This measurement, however, is not covered in this part of ISO 11810.

The results of this part of ISO 11810 are not to be applied to other wavelengths and temporal formats.

The 20 W CO_2 laser (continuous wave) has been selected as the laser to be used for this part of ISO 11810.

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, the power settings and modes of delivery need to be explicitly stated.

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 11810-1, *Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Part 1: Primary ignition and penetration*