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a YrcXUnUi [ cHj`UbY`cXdcfbcgh]`dfch]`UgYf1`nU\_]fi fy\_YnUghf\_Y]b#U]`nU  
j Ufcj UbUdc\_f]j UUnUdUWYbhY**

Optics and optical instruments - Lasers and laser-related equipment - Test method for the laser-resistance of surgical drapes and/or patient-protective covers (ISO 11810:2002)

Optik und optische Instrumente - Laser und Laseranlagen - Prüfverfahren zur Laserresistenz von Operationstüchern und/oder andere Abdeckungen zum Schutz des Patienten (ISO 11810:2002) **(standards.iteh.ai)**

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Optique et instruments d'optique - Lasers et équipements associés aux lasers - Méthode d'essai de la résistance au laser des draps chirurgicaux et/ou des couvertures de protection des patients (ISO 11810:2002)

**Ta slovenski standard je istoveten z: EN ISO 11810:2002**

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**ICS:**

11.140	Oprema bolnišnic	Hospital equipment
13.340.99	Druga varovalna oprema	Other protective equipment
31.260	Optoelektronika, laserska oprema	Optoelectronics. Laser equipment

**SIST EN ISO 11810:2003**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11810**

September 2002

ICS 11.140; 13.340.99; 31.260

English version

**Optics and optical instruments - Lasers and laser-related  
equipment - Test method for the laser-resistance of surgical  
drapes and/or patient-protective covers (ISO 11810:2002)**

Optique et instruments d'optique - Lasers et équipements  
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Optik und optische Instrumente - Laser und Laseranlagen -  
Prüfverfahren zur Laserresistenz von Operationstüchern  
und/oder andere Abdeckungen zum Schutz des Patienten  
(ISO 11810:2002)

This European Standard was approved by CEN on 19 August 2002.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

**Management Centre: rue de Stassart, 36 B-1050 Brussels**

## EN ISO 11810:2002 (E)

<b>CORRECTED 2002-10-16</b>
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**Foreword**

This document (ISO 11810:2002) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 123 "Lasers and laser-related equipment", 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 March 2003, and conflicting national standards shall be withdrawn at the latest by March 2003.

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 relationship with EU Directive(s), see informative Annex ZB, 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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**Endorsement notice**

SIST EN ISO 11810:2003

The text of ISO 11810:2002 has been approved by CEN as EN ISO 11810:2002 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

## Annex ZA (normative)

### Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 139	1973	Textiles - Standard atmospheres for conditioning and testing	EN 20139	1992
ISO 11145	2001	Optics and optical instruments - Lasers and laser-related equipment - Vocabulary and symbols	EN ISO 11145	2001
ISO 11146	1999	Laser and laser-related equipment - Test methods for laser beam parameters - Beam widths, divergence angle and beam propagation factor	EN ISO 11146	1999

## EN ISO 11810:2002 (E)

**Annex ZB**  
(informative)

**Relationship of this document with EC Directives**

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(s) :

- EC Directive 93/42/E(E)C

Compliance with this document provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

**WARNING:** Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this document.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

**Table ZB.1— Correspondence between this European Standard and EU Directives**

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
The whole standard	§§ 1; 2; 3; 4; 7.1; 9.2; 9.3; 11.1; 11.3; 12.7.5; 13.1	The test method only

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# INTERNATIONAL STANDARD

**ISO**  
**11810**

First edition  
2002-09-15

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## **Optics and optical instruments — Lasers and laser-related equipment — Test method for the laser-resistance of surgical drapes and/or patient-protective covers**

*Optique et instruments d'optique — Lasers et équipements associés aux  
lasers — Méthode d'essai de la résistance au laser des draps chirurgicaux  
et/ou des couvertures de protection des patients*

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daf660253e54/sist-en-iso-11810-2003](https://standards.iteh.ai/catalog/standards/sist/1c03cc84-9df6-4d4a-af0c-daf660253e54/sist-en-iso-11810-2003)



Reference number  
ISO 11810:2002(E)

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## ISO 11810:2002(E)

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**ISO 11810:2002(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11810 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 9, *Electro-optical systems*.

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## Introduction

Only a small number of laser applications in medicine require laser-resistant surgical drapes and/or other patient-protective covers. Surgical drapes and/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 and/or other patient-protective covers are not necessarily laser-resistant, specifically designed 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 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. fiberoptic illumination systems, electrosurgical units, hot wire cauteries, etc., this test method addresses only the laser ignition source. While it may not be necessary for all materials used in combination with laser equipment to possess laser-resistance, a surgical drape or other patient-protective cover that claims to be laser-resistant must be tested according to this International Standard. CO<sub>2</sub> lasers may provide the most challenging conditions of all medical lasers, but this is not certain. Ignition/flammability 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. Nevertheless, the 20 W CO<sub>2</sub> laser (continuous wave) has been selected as the default laser for this International Standard. The structure of this International Standard is sufficiently general so that it can be performed using other wavelengths, power settings and modes of delivery. When a CO<sub>2</sub> laser is used in testing under this International Standard, in no case should it have a power level less than 20 W. Users of this test method are cautioned that the laser-resistance of a surgical drape and/or other patient-protective cover will be wavelength sensitive and that a surgical drape and/or other patient-protective cover shall be tested at the wavelength for which it is intended. If used, those other wavelengths, power settings and modes of delivery need to be explicitly stated.

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