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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

*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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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).

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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.

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.