



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 15004-2:2007

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2007)

Ophthalmische Instrumente -
Grundlegende Anforderungen und
Prüfverfahren - Teil 2: Schutz gegen
Gefährdung durch Licht (ISO

Instruments ophtalmiques - Exigences
fondamentales et méthodes d'essai -
Partie 2: Protection contre les dangers de
la lumière (ISO 15004-2:2007)

02/2007



National Foreword

This European Standard EN ISO 15004-2:2007 was adopted as Luxembourgish Standard ILNAS-EN ISO 15004-2:2007.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

THIS PUBLICATION IS COPYRIGHT PROTECTED

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2007)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumière (ISO 15004-2:2007)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2007)

This European Standard was approved by CEN on 10 February 2007.

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: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 15004-2:2007) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", 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 August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes EN ISO 15004:1997.

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 United Kingdom.

Endorsement notice

The text of ISO 15004-2:2007 has been approved by CEN as EN ISO 15004-2:2007 without any modifications.

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2: Light hazard protection

*Instruments ophtalmiques — Exigences fondamentales et méthodes
d'essai —*

Partie 2: Protection contre les dangers de la lumière



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms, definitions and symbols	1
3.1 Terms and definitions	1
3.2 Symbols	5
4 Classification	6
5 Requirements	6
5.1 General	6
5.2 Requirements for classification as a Group 1 instrument	6
5.3 Requirements for Group 2 instruments	7
5.4 Emission limits for determination of Group 1 classification	7
5.5 Emission limits and guideline values for Group 2 instruments	11
6 Test methods	16
6.1 General	16
6.2 Measurements made to classify instruments into Group 1 or Group 2	16
6.3 Group 2 instruments: Measurements	16
6.4 Determination of area	17
6.5 Group 2 instruments: Determination of time and number of pulses to reach maximum exposure guidelines	17
7 Information supplied by the manufacturer	18
Annex A (normative) Spectral weighting functions	20
Annex B (informative) Product-related International Standards for ophthalmic instruments to which ISO 15004-2 applies and which contain a specific light hazard section	26
Annex C (informative) Measurement instruments	27
Annex D (normative) Measurement methods for radiance/irradiance	28
Annex E (informative) Guidance on the direct measurement of irradiance	33
Annex F (informative) Classification flowchart	35
Bibliography	37

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 2.

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

ISO 15004-2 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition, together with ISO 15004-1, cancels and replaces ISO 15004:1997. All reference to light hazard (definitions 3.4 to 3.9, subclause 6.3, subclause 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to the present part of ISO 15004 and has been technically revised.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

- *Part 1: General requirements applicable to all ophthalmic instruments*
- *Part 2: Light hazard protection*