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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 47498.2-2026

**Ophthalmic instruments - Fundamental requirements and test
methods - Part 2: Light hazard protection**
(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1.Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 2 of GB (T) 47498 "Basic Requirements and Test Methods for Ophthalmic Instruments". GB (T) 47498 has been issued.

The following parts were laid out.

---Part 1.General Requirements for Ophthalmic Instruments;

---Part 2.Protection against light hazards

This document is modified to adopt ISO 15004-2.2024 "Ophthalmic instruments - basic requirements and test methods - part 2.protection against light hazards".

This document has undergone the following structural adjustments compared to ISO 15004-2.2024.

---Sections 5.2.2 to 5.2.4 correspond to sections 5.2.1 to 5.2.3 of ISO 15004-2.2024;

---Sections 5.3.2 to 5.3.5 correspond to sections 5.3.1 to 5.3.4 of ISO 15004-2.2024;

---C.7.2~C.7.3 correspond to C.7.1~C.7.2 of ISO 15004-2.2024.

The technical differences between this document and ISO 15004-2.2024, and the reasons therefor, are as follows.

---ISO 15004-1 (see Chapter 3) has been replaced with the normatively referenced GB/T 47498.1 to adapt to my country's technical conditions;

---Added normative reference GB 9706.1-2020 (see 7.3.2);

---Added normative reference GB/T 31523.1-2015 (see 7.3.3);

---The ISO and IEC databases in the "Terms and Definitions" section (see Chapter 3) have been removed to accommodate my country's technical requirements;

---The unused term "emission limit" has been removed from the document, and subsequent entry numbers are sequentially added to facilitate standard implementation;

---The instrument classification guidance flowchart has been revised (see 4.1), removing intermediate processes involving international standards to better suit my country's technical requirements.

condition;

---The symbols, quantities, and units of HB-R have been added (see Table 1 in 5.1) to facilitate the implementation of the standard;

---The radiation measurement formula in row 7 of Table 3 (see Table 3 in 5.6) has been modified to facilitate the implementation of the standard;

---The descriptions of the large spot range in row 8 of Table 3 and row 8 of Table 5 have been revised (see Tables 3 and 5 in section 5.6) to better reflect the characteristics of large spots.

Definitions facilitate the implementation of standards;

---The warning statements A and B in section 7.2.3.2 (see 7.2.3.2) have been separated for easier implementation of the standard;

---The source of the "Follow the operating instructions" safety label has been changed (see 7.3.2, Appendix F) to facilitate the implementation of the standard.

The following editorial changes have been made to this document.

---Change "Special International Standard" to "Special Standard" (see Chapter 1) to suit my country's technical conditions;

---The footnotes have been rearranged to follow the order of the text in Tables 3 and 5, and footnote numbers have been added (see Tables 3 and 5);

--- A typographical error in 7.2.3.1 has been corrected, changing "Table 2, row 3" to "Table 3, row 7";

---The indexing description for Figure C.1 has been changed (see Appendix C);

--- A typographical error in formula (D.4) has been corrected by changing alpha to Theta (see Appendix D);

---Corrected a printing error in E.4.5g)3), changing " $4 \times 2.5 \times (2.05 \times 10^{-2})^{1/4}$ " to " $2.5 \times (2.05 \times 10^{-2})^{1/4}$ ".

(See Appendix E);

---Based on the reference in 7.3.3, the serial numbers of the "Caution. Light Radiation" and "Caution. Laser" labels have been interchanged (see Appendix F).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Medical Products Administration.

Introduction

GB (T)47498 "Basic Requirements and Test Methods for Ophthalmic Instruments" is proposed to consist of two parts.

---Part 1. General Requirements for Ophthalmic Instruments. The purpose is to establish general requirements and testing guidelines applicable to all types of ophthalmic instruments.

Verification method.

---Part 2. Protection against light hazards. The purpose is to establish the requirements and test methods that need to be followed for light hazards applicable to ophthalmic instruments.

Basic requirements and test methods for ophthalmic instruments

Part 2. Protection against light hazards

1 Scope

This document specifies the basic requirements for the safety of light radiation from ophthalmic instruments and describes the corresponding test methods.

This document applies to all ophthalmic instruments that directly project light radiation into or onto the eye, as well as treatment or surgical systems used for...

The part of the device that directs light radiation directly into or onto the eye for diagnostic, illumination, measurement, imaging, or aiming purposes is also suitable for ophthalmic treatment.

Therapeutic light is applied to non-targeted tissues during preparation.

If the instrument-specific standard contains specific light hazard requirements that differ from those in this document, the instrument-specific standard shall take precedence.

This document does not apply to therapeutic light used in treatment devices to irradiate targeted tissues.

Note: In this document, the wavelength range of optical radiation is 250nm~2500nm.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 9706.1-2020 Medical electrical equipment - Part 1. General requirements for basic safety and basic performance (IEC 60601-1)

2012, MOD)

GB/T 31523.1-2015 Security Information Identification Systems - Part 1. Marking (ISO 7010.2011, MOD)

GB/T 47498.1 Basic requirements and test methods for ophthalmic instruments - Part 1. General requirements for ophthalmic instruments (GB/T 47498.1-

2026, ISO 15004-1.2020, MOD)

3 Terms and Definitions

The terms and definitions defined in GB/T 47498.1 and the following terms and definitions apply to this document.

3.1

Aperture

Aperture Stop

An opening used to define the measurement of average light radiation.

Note: For spectral irradiance measurements, the opening is typically the entrance to a small integrating sphere placed in front of the entrance slit of the radiometer/spectroradiometer.

3.2

Continuous exposure

Continuous wave (CW)

Radiation lasting 0.25 seconds or longer.

3.3

An ophthalmic instrument designed to expose the eye to one or more sources of continuous wave radiation.