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

GB/T 47498.1-2026

**Ophthalmic instruments - Fundamental requirements and test
methods - Part 1: General requirements applicable to all
ophthalmic instruments**

眼科仪器 基本要求和试验方法 第1部分：眼科仪器通用要求
(English Translation)

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Foreword

This document conforms to GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting is scheduled.

This document is Part 1 of GB (T) 47498 "Basic Requirements and Test Methods for Ophthalmic Instruments". GB (T) 47498 has been published.

The following section.

--Part 1: General Requirements for Ophthalmic Instruments;

--Part 2: Protection against light hazards.

This document is modified to adopt ISO 15004-1:2020 "Ophthalmic instruments - Basic requirements and test methods - Part 1: General requirements for ophthalmic instruments". Require".

Compared with ISO 15004-1:2020, this document has undergone many structural adjustments. A comparison of the structural numbering changes between the two documents is provided below.

See Appendix A for the table.

The technical differences between this document and ISO 15004-1:2020, and the reasons

therefor, are as follows.

-- IEC 60601-1:2005 A1:2012 (see 4.4, 4.8, 4.11.1) has been replaced by the normatively referenced GB 9706.1-2020.

(4.11.2, 5.11.1, 6.1, 6.2), to adapt to my country's technological conditions;

--ISO 15004-2:2007 (see 4.11.2, 6.1) has been replaced with the normatively referenced GB 47498.2-2026 to adapt to my country's national standards.

Technical conditions;

--IEC 60695-2-10 (see 5.5.2) has been replaced with the normatively referenced GB/T 5169.10 to adapt to my country's technical conditions;

--IEC 60695-2-11 (see 5.5.2) has been replaced with the normatively referenced GB/T 5169.11 to adapt to my country's technical conditions;

--The normative reference document GB/T 42062 (see 5.2, 5.9) has been added to adapt to my country's technical conditions;

--The normative reference document GB/T 14710 (see 4.10 and 5.10) has been added to adapt to my country's technical conditions;

--The normative reference document GB/T 16886.1 (see 5.5.1) has been added to adapt to my country's technical conditions;

--The "Environmental Conditions" requirements (see 4.10) have been changed to suit my country's technical conditions;

--The requirement of "IEC 60601-1 non-applicable clause" (see 6.2 of ISO 15004-1:2020) has been removed to accommodate my country's technical requirements.

condition;

--Added a "Design" test method (see 5.2) to adapt to my country's technical conditions;

--A "performance" test method has been added (see 5.3) to adapt to my country's technical conditions;

--A test method for "combinations of different equipment" (see 5.4) has been added to adapt to my country's technical conditions;

--A test method for "biocompatibility" has been added (see 5.5.1) to adapt to my country's technical conditions;

--Added a "pollution prevention" test method (see 5.6) to adapt to my country's technical conditions;

--Added the "Scale and Display" test method (see 5.7) to adapt to my country's technical conditions;

- The test method for "thermal hazard" has been modified (see 5.8) to adapt to my country's technical conditions;
- A "mechanical hazard" test method has been added (see 5.9) to adapt to my country's technical conditions;
- An "Environmental Conditions" test method (see 5.10) has been added to adapt to my country's technical conditions;
- The test method for "Electrical Safety" (see 5.11.1) has been modified to adapt to my country's technical conditions;
- An additional test method for "light radiation hazard" (see 5.11.2) has been added to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

- Added headings to sections 4.5.1 and 4.5.2 (see sections 4.5.1 and 4.5.2) to facilitate the implementation of the standard;
- The phrase "when testing according to 7.1" is changed to "when testing according to 5.5.2" (see 4.5.2) to facilitate the implementation of the standard;
- The list of international standards has been removed, and a list of national and industry standards has been added (see Appendix B) to facilitate the implementation of standards.

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 aim is to establish the requirements and testing procedures applicable to light hazards in ophthalmic instruments.

method.

Basic requirements and testing methods for ophthalmic instruments Part 1: General Requirements for Ophthalmic Instruments

1 Scope

This document specifies the basic requirements for non-invasive ophthalmic instruments (including active and passive ophthalmic instruments) and describes the corresponding testing procedures.

Verification method.

This document applies to non-invasive ophthalmic instruments (including active and passive ophthalmic instruments), and also includes low vision aids and eye care devices.

Pressure gauge.

This document does not apply to other ophthalmic instruments that come into contact with the eyeball, surgical microscopes, endoscopes, or instruments intended for use in ocular laser examinations and laser treatments.

Treatment equipment.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below.

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/T 5169.10 Fire Hazard Testing of Electrical and Electronic Products - Part 10: Basic Test Methods for Glow Wire/Hot Wire General test methods and settings (GB/T 5169.10-2017, IEC 60695-2-10:2013, IDT) GB/T 5169.11 Fire Hazard Testing of Electrical and Electronic Products - Part 11: Basic Test Methods for Glow Wire/Hot Wire - Finished Products Hot Wire Flammability Test Method (GWEPT) (GB/T 5169.11-2017, IEC 60695-2-11:2014, IDT) GB 9706.1-2020 Medical electrical equipment - Part 1: General requirements for basic safety and basic performance (IEC 60601-1.

2012, MOD)

GB/T 14710 Environmental requirements and test methods for medical electrical appliances GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T 42062 Application of risk management to medical devices (GB/T 42062-2022, ISO 14971:2019, IDT) GB 47498.2-2026 Ophthalmic Instruments - Basic Requirements and Test Methods - Part 2: Protection against Light Hazards (ISO 15004-2) 2024, MOD)