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

GB 11239.1-2005

Replacing GB 11239.1-2005

**Optics and photonics - Operation microscopes - Part 1:
Requirements and test methods
(English Translation)**

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Table of Contents

Preface	
Introduction	
1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Requirements	1
5 Test Method	3
6 Mark	9
Appendix A (Informative) Structure Number Comparison Table	10
Appendix B (Informative) List of Technical Differences and Their Causes	12
Reference	14

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1. Structure and drafting rules for standardization documents"

Drafting.

This document is Part 1 of GB/T 11239 Optical and Photonic Surgical Microscopes. GB/T 11239 has been published for the following

part.

--- Part 1. Requirements and test methods.

This document replaces GB 11239.1-2005 "Operating microscopes Part 1. Requirements and test methods" and is consistent with GB 11239.1-2005.

In addition to structural adjustments and editorial changes, the main technical changes are as follows.

--- Deleted the term and definition of "working distance" (see 3.1.2 of the 2005 edition);

--- Deleted the classification (see 3.2 of the 2005 edition);

--- Changed "the field of view between the left and right optical systems should be consistent" (see Table 1, 4.2.1 of the 2005 edition);

--- Added the requirement of "the amount of movement of the parfocal plane when changing the magnification" (see 4.2);

- Deleted the "Environmental requirements" requirement (see 4.4 of the.2005 edition);
- Changed the requirement of "Conversion of temperature rise of the illuminated surface into irradiance" (see 4.7, 4.2.6 of the.2005 edition);
- Added "electromagnetic compatibility" requirements (see 4.12);
- Deleted the inspection rules (see Chapter 5 of the.2005 edition);
- Added the test method of "axial difference between left and right optical systems" (see 5.2.3.3);
- Added the test method of "the amount of movement of the focal plane when changing the magnification" (see 5.2.3.4);
- Added the "electromagnetic compatibility" test method (see 5.12);
- Added "marking" requirements (see Chapter 6);
- Deleted temperature and relative humidity conditions (see 6.1 of the.2005 edition);
- Deleted the "Environmental test" test method (see 6.12 of the.2005 edition);
- Deleted the signs, labels and instruction manual (see Chapter 7 of the.2005 edition);
- Deleted packaging, transportation and storage (see Chapter 8 of the.2005 edition).

This document modifies ISO 10936-1.2017 "Optical and photonic surgical microscopes - Part 1.Requirements and test methods".

Compared with ISO 10936-1.2017, this document has many structural adjustments. The structural number changes between the two documents are shown in the table below.

See Appendix A for the table.

This document has many technical differences compared to ISO 10936-1.2017.

A list of these technical differences and their reasons is given in Appendix B.

The following editorial changes have been made to this document.

- Deleted the URLs of ISO and IEC terminology databases in Chapter 3.

Introduction

GB/T 11239 "Optical and photonic surgical microscopes" is intended to consist of two parts.

--- Part 1.Requirements and test methods. The purpose is to establish general requirements and test methods that need to be followed for all types of surgical microscopes.

Test method.

--- Part 2. Light hazards of ophthalmic surgical microscopes. The purpose is to establish the light hazard requirements applicable to ophthalmic surgical microscopes.

Requirements and test methods to be followed.

Optical and Photonics Surgical Microscopes

Part 1. Requirements and test methods

1 Scope

This document specifies the requirements for surgical microscopes and describes the corresponding test methods.

This document applies to surgical microscopes used for observation during surgical procedures and patient care.

This document does not apply to surgical microscope accessories, such as camera systems.

NOTE: ISO 10936-2 specifies specific requirements for optical radiation hazards associated with ophthalmic surgical microscopes.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to

This document.

GB 9706.1 Medical electrical equipment Part 1. General requirements for basic safety and essential performance (GB 9706.1-2020,

IEC 60601-1.2012, MOD)

GB/T 10050 Optics and optical instruments - Reference wavelengths (GB/T 10050-2009, ISO 7944.1998, IDT)

GB/T 20146 CIE Standard Illuminants for Colorimetry (GB/T 20146-2006, CIE S005.1999, IDT)

JB/T 9328-2024 Resolution Plate

YY9706.102 Medical electrical equipment Part 1-2. General requirements for basic safety and essential performance Collateral standard. Electromagnetic compatibility

Content requirements and tests

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

operating microscope

Stereo microscopes for observing surgical and other medical procedures, consisting of an illumination system and an observation system (including objectives, variable or fixed

It consists of a magnification optical system, an observation tube and an eyepiece.

Example. colposcopy.

4.1 General requirements

The surgical microscope should meet the requirements of 4.2 to 4.12.

All the following requirements are minimum requirements. The reference wavelength complies with the provisions of GB/T 10050.

4.2 Optical and mechanical requirements

Surgical microscopes should comply with the requirements specified in Table 1.

The tests for optical and mechanical requirements shall be carried out in accordance with 5.2.

END: Draft Version (GB/T 11239.1-2025)