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PHARMACEUTICAL INDUSTRY STANDARD
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**Optics and photonics - Operation microscopes -
Light hazard from operation microscopes
used in ocular surgery**

(ISO 10936-2:2010, Optics and photonics - Operation microscopes - Part 2:
Light hazard from operation microscopes used in ocular surgery, MOD)

光学和光子学 手术显微镜 眼科用手术显微镜的光危害

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Foreword

All technical content of this Standard is mandatory.

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard is modified on the basis of adopting ISO 10936-2:2010 *Optics and photonics - Operation microscopes - Part 2: Light hazard from operation microscopes used in ocular surgery*.

Compared with ISO 10936-2:2010, the technical differences and reasons in this Standard are as follows:

On the normative references, this Standard has made the adjustment of technical differences so as to meet the technical conditions of China. The adjustment is reflected in Clause 2 "Normative references". It used GB 11239.1-2005 to replace ISO 10936-1 used as reference in ISO 10936-2:2010.

Attention is drawn to the possibility that some of the elements of this Standard may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by State Food and Drug Administration.

This Standard shall be under the jurisdiction of Subcommittee of National Technical Committee on Medical optics and instruments of Standardization Administration of China (SAC/TC 103 / SC 1).

The drafting organization of this Standard: Zhejiang Medical Device Testing Institute.

Main drafters of this Standard: Wang Jingtao, Jia Xiaohang, He Tao, Peng Jianhua.

Optics and photonics - Operation microscopes - Light hazard from operation microscopes used in ocular surgery

1 Scope

This Standard specifies the basic requirements and test methods for light hazard from operation microscopes used in ocular surgery.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 11239.1-2005, *Operation microscopes Part 1: Requirements and test methods* (ISO 10936.1:2000, MOD)

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 group 1 instrument

the ophthalmic instruments that have no potential light hazard and meet requirements of 5.2 in ISO 15004-2:2007

NOTE: It is quoted from ISO 15004-2:2007.

3.2 group 2 instrument

the ophthalmic instruments that have potential light hazard and cannot meet requirements of 5.2 in ISO 15004-2:2007.

NOTE: It is quoted from ISO 15004-2:2007.

6 Additional information provided by manufacturer for group 2 instruments

6.1 Continuous wave light source with strong variable light intensity shall be indicated in the instructions for use. When the instrument is set at the maximum value and 50% of the maximum value, with or without retinal protection device, it shall meet the time required by the maximum exposure guidance value specified in 6.5.1 of ISO 15004-2:2007 (see Clause 7 of ISO 15004-2:2007).

During the operation, such information shall be obvious to operator (see Clause 7 of ISO 15004-2:2007). Annex A gives the example for how to provide such information.

6.2 If applicable, the pulsed light source with strong variable light shall be indicated in the instructions for use. When the instrument is set at the maximum value and 50% of the maximum value, with or without retinal protection device, it shall meet the number of pulses required by the maximum exposure guidance value specified in 6.5.1 of ISO 15004-2:2007.

7 Marks

The marks for operation microscopes shall be in accordance with the provisions of GB 11239.1-2005.