



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 1296-2016

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

光学和光子学 手术显微镜 眼科用手术显微镜的光危害防护

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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

YY 1296 addresses the light hazard from operating microscopes used in eye surgery. The problem is peculiar to ophthalmology: the microscope illuminates the retina directly, through a pupil that has been pharmacologically dilated and an eye whose blink and aversion reflexes are abolished, for the length of an operation. Retinal phototoxicity from prolonged

microscope exposure during cataract surgery is documented. This standard sets the requirements that limit that exposure and the test methods that verify them, covering the spectral output, the retinal irradiance and the exposure time limits the manufacturer has to state. Cataract surgery is the highest-volume operation in Chinese ophthalmology. Being a YY standard without the /T suffix, compliance is compulsory in China.

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.

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