

YY

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

YY 0763-2009

Medical endoscopes - Fibre optic cables for lighting

医用内窥镜照明用光缆

Issued on: May 1, 2023

Implemented on: June 1, 2011

Issued by: National Medical Products Administration

Table of Contents

1	Scope
2	Normative references
3	Terms and definitions
4	Requirements
4.1	Dimensions
4.2	Optical performance
5	Test method
5.2	Determination of light output angle
5.5	Torsional test
5.5.1	Determination of luminous flux output
5.6	Momentarily flattening test
5.9	Test of impact due to falling
5.9.1	Devices
7	References and Original Chinese Documents...

Foreword

This standard was proposed by and under jurisdiction of the National Technical Committee of Optics & Optical Instruments of Standardization Administration of China (SAC/TC103/SC1). The drafting organization of this standard is State Food and Drug Administration Hangzhou Centre for Medical Devices Quality Supervision and Testing. Chief drafting staffs of this standard include Yan Qinglai, Jia Xiaohang, Ma Jun and Zhang Qinyuan. Medical endoscopes - Fibre optical cables for lighting

1 Scope

YY 0763 is the mandatory Chinese standard for the fibre optic light cables that carry illumination from the light source to a medical endoscope. It sets the requirements such a cable has to meet and the test methods that verify them, covering light transmission and how much of it survives the cable, the connectors at each end, the resistance to bending and to repeated sterilization, and the heat that a high-intensity source puts into the fibre bundle. A light cable that has lost half its fibres still works, just dimly, and the surgeon compensates by turning the source up, which puts more heat into a cable already failing. Being a YY standard without the /T suffix, compliance is compulsory in China. The standard carries Amendment 1 of 2023.

This standard specifies the scope, terms and definitions, requirements, and test methods of fibre optical cables for lighting of the medical endoscopes. This standard applies to fibre optical cables, which may be used as independent products, used for normal lighting of examination and operation together with medical endoscopes. NOTE Normal fibre optical cables refer to those not for special purpose of application.

2 Normative references

The following standards contain provisions which, through reference in this standard, constitute provisions of this standard. For dated references, subsequent amendments (excluding any correction) or revisions are not applicable to this standard. However, parties who mutually agree to this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the respective normative document is applicable to this standard.

GB 9706.1 - 2007 Medical electrical equipment - Part

3 Terms and definitions

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

3.1 light input surface the effective light transmission surface of the joint between fibre optical cable and cool light-illuminator.

3.2 light output surface the effective light transmission surface of the joint between fibre optical cable and medical endoscope.

3.3 initial condition the condition that the fibre optical cable has been never inspected or tested under the applied force in accordance with this standard; and is placed naturally, horizontally and straightly.

4.2 Optical performance

4.2.1 Light output angle In the instructions for use, the manufacturer shall state the nominal value of the light output angle of the fibre optical cables, with permissible tolerance of $\pm 10\%$.

4.3.1 Torsion Under torsional condition, the light transmission performance of the fibre optical cable shall not be less than 90% of performance of initial condition.

4.3.2 Momentary flattening Under momentarily flattened condition, the light transmission performance of the fibre optical cable shall not be less than 90% of initial-condition.

4.3.3 Tension After axially tensional test, the light transmission performance of the fibre optical cable shall not be less than 90% of performance of initial condition.

4.3.4 Minimum bendable radius In the instructions for use, the manufacturer shall state the

minimum bendable radius of the fibre optical cable. After the fibre optical cable is tested by bent to the minimum bendable radius, its light transmission performance shall not be less than 90% of performance of initial condition.

4.4 General requirements The light input surface and light output surface of the fibre optical cable shall be bright and clean, smooth and neat, and free of notch. The external surface shall be continuously smooth; and free of sharp edge, burr, cracking and other defects which may possibly result in hazard to human body.

4.5 Disinfection Repetitively disinfected for 20 times according to the instructions for use, the light transmission performance of the fibre optical cable shall not be less than 90% of performance of initial condition.

4.6 Dielectric strength After the moist pre-treatment, the fibre optical cable is tested for 1 min under an effective sinusoidal 1,500 VAC

50 Hz voltage which is applied to the end of the light input surface and the end of the light output surface. There shall be no breakdown and flashover.

4.7 Designation The fibre optical cable shall be designated with classification mark of BF type, in accordance with those specified in sub-clause

6.1 of GB 9706.1 - 2007.

5 Test method

5.1 Dimensions General measuring tools shall be used for measurement.

5.2 Determination of light output angle

5.2.1.1 Light illuminator At spectrum ranging from 380 nm to 780 nm, the light illuminator to be used shall be continual, stable, spectrum-rich, and capable of adjusting the output of light intensity. The stability of the light intensity output shall be within $\pm 2\%$.

5.2.1.2 Injection device **5.2.1.2.1 Integrating sphere** For the integrating sphere to be used, the total area of the opening holes shall not exceed 10% of the whole spherical area inside the sphere. **5.2.1.2.2 Cosine radiation panel** A transmission-type cosine radiation panel shall be used. The luminance unevenness at each point and in any direction shall not be greater than 5%. Those opening holes, their area bigger than the integrating sphere, shall be placed at the light output opening of the integrating sphere; closely against the light input surface; and perpendicular to the mechanically positioning axis of the light input surface of the fibre optical cable.

5.2.2 Ambient conditions Under the testing environment, the dark luminance shall be controlled not greater than 1 lx.

5.2.3 Steps Fix the end of the light input surface of the fibre optical cable. Let the cosine

radiation panel be placed against the light input surface of the fibre optical cable. Adjust the illuminator to appropriate light intensity.

5.2.4 Calculation The average light output angle, θ , is determined according to Equation (1).

5.4 Calculation of light transmission rate Ranging from 380 nm to 780 nm, the light transmission rate, T , corresponding to D

65 Standard Illuminant is determined according to Equation (3).

5.6 Momentarily flattening test

5.6.1 Devices They are shown in Figure 5.

5.9.1 Devices

5.9.1.1 Special wooden board for testing It is a 50-mm-thick hard wooden board (for example, made of hard wood with density greater than 700 kg/m³).

5.10 General required inspections They include visual observation, hand-feeling, and operating inspection.

5.11 Disinfection test The fibre optical cable is repetitively disinfected for 20 times according to the method specified in the instructions for use. Measure the luminous flux output in accordance with those specified in sub-clause 5.5.1. Compare it to the measured value from sub-clause 5.5.2.

5.12 Dielectric strength test The fibre optical cable is moist-pretreated in accordance with those specified in sub-clause

4.10 of GB 9706.1-2007, and then tested in accordance with sub-clause

20.4 of GB 9706.1-2007.

5.13 Check of marking Test shall be carried out in accordance with sub-clause