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

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**General requirements for the medical endoscope and
endoscope accessories
(English Translation)**

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Foreword

This Standard is developed in accordance with the international standard ISO

8600.1997 "Medical endoscopes and endoscopic accessories". In terms of technical content, it is not equivalent to ISO 8600.1997.

Used in conjunction with this Standard is GB 9706.19-2000 "Medical electrical equipment - Part 2.Particular requirements for the safety of endoscopic equipment". The main technical differences between this Standard and ISO

8600 are as follows.

- Incorporate all the inspection methods of ISO 8600-3 and ISO 8600-4 and the inspection provisions of ISO 8600-1 into this Standard.
- According to the actual situation of China, the environmental test adopts the relevant regulations of GB/T 14710.
- ADD the requirement of coincidence of lighting source and observation field of view.
- The shape and size of the eyepiece are identical to the requirements of DIN58105 "Requirements and inspection of medical endoscopes".

- ADD the requirements for inspection rules, packaging, transportation and storage.

[Translator note. The original text is reformatted to items, for ease of reading]

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of National Technical Subcommittee on Medical Optics and Instruments of Standardization Administration of China.

Drafting organization of this Standard. Shanghai Medical Optical Instrument Co., Ltd.

Main drafters of this Standard. Mai Xiuqin, Li Yafen, Xue Xiaoguo, Qian Xiaoyang.

General requirements for the medical endoscope and endoscope accessories

1 Scope

This Standard gives the terminology, general technical requirements, general test methods, inspection rules, marking, instructions for use, packaging, transportation and storage of endoscope and endoscope accessories used in medical clinics. The particular technical requirements for various types of endoscopes shall meet the requirements of the corresponding particular standards.

2 Normative references

The following documents contain provisions which, through reference in this Standard, constitute provisions of this Standard. For the dated references, their subsequent amendments (excluding corrections) or revisions do not apply to this Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest editions of these documents are applicable. For undated reference documents, the latest editions apply to this Standard.

GB/T 191-2000 Packaging - Pictorial marking for handling of goods

GB 9706.19-2000 Medical electrical equipment - Part 2.Particular requirements for the safety of endoscopic equipment (idt IEC 60601-2-18.1996)

3 Terms and definitions

The following terms and definitions apply to this Standard.

3.1

Endoscope

Medical instruments for observation purposes, with or without lenses; medical devices which go deep into the natural or surgically opened pores of the human body for examination, diagnosis or treatment.

3.2

Endoscope accessory

Medical devices which can penetrate the endoscope into the natural or surgically opened pores of the human body; or medical devices which can be used for inspection, treatment, or diagnosis with an endoscope.

3.3

Rigid endoscope

The endoscope (endoscope accessory) of which the insertion portion cannot be bent into the human body's natural or surgically opened pore or instrument channel.

3.4

Flexible endoscope

The endoscope (endoscope accessory) of which the insertion portion can freely bend into the human body's natural or surgically opened pore or instrument channel.

3.5

French; Fr

The measurement method for the size of the endoscope with circular or non-circular cross-section, which is defined as.

4.2 Maximum insertion portion width

The maximum insertion portion width must not be larger than the size specified in the instructions for use provided by the manufacturer. See 8.2 c).

4.3 Minimum insertion channel width

The minimum insertion channel width must not be less than the size specified in the instructions for use provided by the manufacturer. See 8.2 h).

4.4 Field of view

If the manufacturer has no other special regulations, the deviation of the field of view of optical endoscope from the nominal value provided by the manufacturer shall not exceed 15%. In the product catalog and manual materials, the description of the field of view is not mandatory.

4.7 Coincidence of lighting source and observation field of view

At the working distance, the illumination spot shall fill the field of view, without obvious dividing line between bright and dark.

4.8 Safety

Endoscopes and endoscope accessories shall meet the requirements of GB 9706.1.

4.9 Biocompatibility

The outer surface material of the insertion portion is an external access device, which is in short-term contact with the tissue. Its biocompatibility shall be evaluated according to the requirements of GB/T 16886.1-2001.

5.1 Surface and edge

Under sufficient lighting, use visual inspection and hand feel inspection. It shall meet the requirements of 4.1, without the need for magnifying tools.