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Medical endoscopes – Rigid endoscope –

Part 4: Fundamental requirement

医用内窥镜-硬性内窥镜-第 4 部分：基本要求

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Table of Contents

Medical endoscopes – Rigid endoscope –

Part 4: Fundamental requirement

1 Scope

This part of YY 0068 specifies the fundamental requirements for the rigid endoscope for medical purposes.

2 Normative references

The provisions in following documents become the provisions of this part through reference in this part. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this part; however, parties who reach an agreement based on this part are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 9706.1-2007 Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988, IDT)

GB 9706.19 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment (GB 9706.19-2000, idt IEC 60601-2-18:1996)

GB 11244-2005 General requirements for the medical endoscope and endoscope accessories

GB 18278 Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization (GB 18278-2000, idt ISO 11134:1994)

GB 18279 Medical devices - Validation and routine control of ethylene oxide sterilization (GB 18279-2000, idt ISO 11135:1994)

GB 18280 Sterilization of health care products - Requirement for validation and routine control - Radiation sterilization (GB 18280-2000, idt ISO 11137:1995)

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997, IDT)

GB/T 16886.7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (GB/T 16886.7-2001, idt ISO 10993-7:1995)

GB/T 19000 Quality management systems—Fundamentals and vocabulary (GB/T 19000-2008, idt ISO 9000:2005)

GB/T 19633-2005 Packaging for terminally sterilized medical devices (ISO 11607:2003, IDT)

YY 0068.1 Medical Endoscopes - Rigid Endoscope - Part 1: Optical properties and test methods

YY 0068.2 Medical endoscopes - Rigid endoscope - Part 2: Mechanical properties and test methods

YY 0068.3 Medical endoscopes - Rigid endoscope - Part 3: Marking and instruction manual

YY/T 0287 Medical devices - Quality management systems - Requirements for regulatory purposes (YY/T 0287-2003, idt ISO 13485:2003)

YY/T 0297 Clinical investigation of medical devices (YY/T 0297-1997, idt ISO 14155:1996)

YY/T 0316 Medical devices - Application of risk management to medical devices (YY/T 0316-2008, idt ISO 14971:2007)

People's Republic of China Pharmacopoeia, 2005 version, two volumes

3 Terms and definitions

The terms and definitions in the other parts of YY 0068 apply to this part.

4 General provisions

The safety and performance of rigid endoscopes shall be subjected to both preclinical and clinical evaluations, including appropriate risk analysis in accordance with YY/T 0316.

In accordance with the relevant provisions of YY/T 0297, MAKE clinical evaluation against the rigid endoscope, AND it shall be able to certify that the endoscope is clinically safe and effective.

9 Manufacturing

Endoscopes shall be produced in a manner that guarantees design characteristics.

The quality system shall comply with the requirements of YY/T 0287 and/or related laws and regulations.

10 Disinfection and sterilization

10.1 Endurance of repeatable disinfection or sterilization product

For rigid endoscopes that can be repeatedly disinfected or sterilized, the method of disinfection or sterilization shall neither impair the functioning of the product NOR cause corrosion.

The test can be made by repeating 20 times of disinfection or sterilization as specified in the instruction manual. For the soaking disinfection method, it may also use the duration 20 times the soaking duration as specified in the instruction manual.

10.2 Sterile provision of products

For sterile products, the sterile process shall be effective and controlled. Products shall be indicated as “sterile”, AND the sterilization assurance level (SAL) shall not exceed 10^{-6}.

If other sterilization assurance levels are used, the manufacturer shall provide a risk assessment document to prove it.

If using the ethylene oxide sterilization, it shall meet the requirements of GB 18279.

If using the radiation sterilization, it shall be consistent with the requirements of GB 18280.

If using the industrial damp heat sterilization, it shall be consistent with the requirements of GB 18278.

As for the sterile inspection, it may use the test method in People’s Republic of China Pharmacopoeia (2005 version), two volumes.

For ethylene oxide sterilized products, ethylene oxide residues shall not exceed the limits given in GB/T 16886.7.