YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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Replacing YY 91075-1999

Rigid hysteroscope

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Table of Contents

Foreword

This standard is a revision of YY 91075-1999 “Hysteroscope”.

As compared with YY 91075-1999, the main changes of this standard are as follows:

- ADD the classification and marking;
- STANDARDIZE the standard’s name;
- DIVIDE the hysteroscope into two types: inspection hysteroscope and surgery hysteroscope. Surgery hysteroscope is further divided into two types: integrated and split;
- MAKE specific parameters and technical requirements for the two types of hysteroscope, respectively;
- ADD the biocompatibility requirements.

The electrical connection part fully implements the relevant provisions of GB 9706.1-1995 “Medical electrical equipment - Part 1: General requirements for safety” and GB 9706.19-2000 “Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment”. The specific content is given in the form of Appendix A (normative).

Appendix A of this standard is a normative appendix.

This standard was approved by the China Food and Drug Administration.

This standard was proposed by and shall be under the jurisdiction of the National Technical Committee for Standardization of Medical Optics and Instruments.

Drafting organization of this standard: Shenyang Shenda Endoscope Co., Ltd.

The main drafters of this standard: Jiang Kerang, Gao Mingxian, Zhang Chang’an.

This standard replaces the standard previously issued as follows:

- ZB C36001-1985;
- YY 91075-1999.

Rigid hysteroscope

1 Scope

This standard specifies the classification and marking, requirements, test methods, inspection rules, signs, labels and instructions for use, packaging, transportation, storage of rigid hysteroscope.

This standard applies to rigid hysteroscope (hereinafter referred to as hysteroscope). Hysteroscope is mainly used in the medical clinical diagnosis of uterine cavity disease and treatment together with surgery instruments.

This standard does not apply to high-frequency electric hysteroscope.

2 Normative references

The provisions in following documents become the provisions of this standard through reference in this standard. For the dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this standard; however, parties who reach an agreement based on this standard 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/T 191-2000 Packaging - Pictorial marking for handling of goods

GB/T 2829-2002 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)

GB/T 6463-2005 Metallic and other inorganic coatings - Review of methods of measurement of thickness

GB 9706.1-1995 Medical electrical equipment - Part 1: General requirements for safety (idt IEC 601-1:1988)

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

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

GB/T 14710-1993 The environmental requirements and test methods for medical electrical equipment

GB/T 16886.1-2001 Biological evaluation of medical devices - Part 1: Evaluation and testing (idt ISO 10993-1:1997)

GB/T 16886.5-2003 Biological evaluation of medical devices - Part 5: Test for in vitro cytotoxicity (ISO 10993-5: 1999, IDT)

GB/T 16886.10-2005 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002, IDT)

YY 0068 General technical conditions for medical rigid endoscopes

YY 0076-1992 Coating classifications for metal product - Technical conditions

YY 0466-2003 Medical devices - Symbols to be used with medical device labels labelling and information to be supplied (ISO 15223:2000, IDT)

3 Classification and composition

3.1 Classification

Hysteroscope may be divided into two types: inspection hysteroscope and surgery hysteroscope. Surgery hysteroscope is further divided into two types: integrated and split.

3.2 Composition

3.2.1 The inspection hysteroscope consists of an endoscope, a sheath, an obturator, a light guide.

3.2.2 The integrated surgery hysteroscope consists of an endoscope with an instrument channel and a fluid-injection channel as well as a light guide; the split surgery hysteroscope consists of an endoscope, a sheath, an obturator, a manipulator, a light guide.

4 Requirements

4.1 Hysteroscope is a rigid endoscope product. In addition to the following requirements, it shall also comply with the general requirements of YY 0068.

4.2 Surface and edge: The components of the hysteroscope shall be designed so as not to cause any accidental injury to the human body, all surfaces must be free of pores, cracks and burrs.

4.3 The basic dimensions of hysteroscope shall meet the requirements of Table

g) For the endoscope whose front end is curved, the curved end shall be firm and reliable, the outer surface shall be smooth and tidy, there shall be no light leakage;

h) For the endoscopes that can be sterilized by pressure steam, after the test, the resolution and illuminance of the endoscope shall be not less than 95% of the original value.

4.6 The sheath and manipulator shall meet the following requirements:

a) The connection of the sheath, the manipulator, the obturator, the endoscope shall be firm and reliable;

b) Each water-passing valve shall be flexible in rotation, the water-passing valve and connection part shall be well sealed, the water seepage shall be not more than five drops in 1 min;

c) The manipulator with the guide plate shall have flexible guiding plates, the rotation of the rotating hand-wheel shall be flexible and reliable;

d) The endoscope or the instrument channel of the manipulator, the water-injection channel shall be clean and unobstructed. The instrument channel shall enable the matching surgery instruments to pass smoothly, the instrument's head shall be located in the field of view.

4.7 The flowrate of the hysteroscope's water injection channel shall not be less than 130 mL/min.

4.8 The surface of the hysteroscope's limiting stopper shall be smooth, reliable to position, easy to move.

4.9 The welding part of the hysteroscope shall be firm and reliable, flat and smooth, without the phenomenon of de-soldering or surfacing.

4.10 The plating of hysteroscope's plated components shall comply with the category-V grade-2 requirements of YY 0076-1992.

4.11 Hysteroscope is a medical device that is in short-term contact with the damaged surface. The outer surface material of the insertion part shall be made of materials that have been proven to be biocompatible. Otherwise, the following tests shall be carried out:

a) The cytotoxicity score shall be not more than 1;

b) The type of stimulus reaction shall be not more than mild;

c) There shall be no sensitization.

Use general purpose or special gauge to carry out test, the results shall comply with the requirements for dimensions in clauses 4.3 and 4.4. If the cross-section of the insertion part is non-circular, measure the minimum length U of the circumscribed curve, then use the formula (1) to calculate the value of F_r, which shall meet the requirements of 4.3.

$$F_r = 3\,U/\pi \qquad \cdots\cdots(1)$$

Where:

F_r - The equivalent perimeter, in millimeters (mm);

U - The minimum length of the externally-tangent curve, in millimeters (mm).

5.3 Basic parameters of endoscope

5.3.1 Field of view and angle of view

5.3.1.1 Method-1

5.3.1.1.1 The measuring instrument consists of the following parts:

a) Optical bench or similar device, which can support the endoscope for testing, it may adjust the optical axis of the endoscope to coincide with the center of the measuring target. At the end surface of the endoscope's head, measure the field of view at a point along the perpendicular direction 50 mm from the center point of the measuring target of the concentric circle where the angle is marked;

b) The target holder and the dial divided by "degrees" (see Figure 1);

c) Measuring target for the measurement of field of view and angle of view (see Figure 2): circular, with a set of measurements in unit of "degree", measured at 50 mm. The ring of the measuring target may be calculated according to the formula (2):

$$D = 100\,\tan(\beta/2) \qquad \cdots\cdots(2)$$

Where:

D - The diameter of the measuring ring corresponding to different angles of view, in millimeters (mm);

β - Field of view, in degrees (°).

The measuring target is fixed on the instrument.

There shall be a main marking line every 10°, as well as the

5.3.4 Illuminance

In an environment where the dark illuminance is less than 1% of the measured illuminance, use a light guide to connect the endoscope to a 150 W halogen cold light source, place the illuminometer probe at the working distance of the endoscope, turn on the cold light source, adjust the illuminance value of the light source to the maximum, the illuminometer's reading shall meet the requirements of 4.4 and 4.5.7.

5.3.5 Clearly observable range

Fix the endoscope and adjust the distance between the objective lens and the object to be observed. When the distance is between 3 mm and 50 mm, it may clearly observe a 1.2 mm width line through the endoscope's eyepiece, which shall comply with the requirements of clause 4.4.

5.4 Endoscope's performance

5.4.1 Defect and light spot of field of view

Turn on the cold light source and adjust to the brightest state. Observe the illuminated white paper through the endoscope, which shall meet the requirements of 4.5.1 and 4.5.5.

5.4.2 Test of half-unshielded eyepiece cover

It is tested according to the method of 5.5 in GB 11244-2005, the results shall meet the requirements of 4.5.2.

5.4.3 Test of fog layer

Insert the insertion part of the endoscope into water which has a temperature of 20 °C or less. After 10 min, take it out. Then insert it into water which has a temperature of 40 °C. Take it out and wipe it dry. Observe from the eyepiece, it shall meet the requirements of 4.5.3.

5.4.4 Sealing test

It is tested according to the method specified in YY 0068-1992, the results shall comply with the requirements of 4.5.4.

5.4.5 Illuminance uniformity

Place the illuminometer probe at a distance of 50 mm in front of the endoscope. According to the angle of view of the endoscope, adjust the illuminometer probe, to make it perpendicular to the view direction of the endoscope.

At the point A (A is the center of the field of view at the object side) in Figure 4,

5.7 Test of limiter movement

Simulate the action of use, use hand-touching to carry out test, which shall meet the requirements of 4.8.

5.8 Test of plating

Before the test, use a clean soft cloth or cotton yarn to remove the oil stain on the surface of the specimen. When testing, it shall be visually observed under the following conditions:

a) Place the specimen on a non-reflective white platform or in the white transmitted light without reflected light;

b) The illuminance is 200 lx ~ 300 lx (equivalent to illuminance at 500 mm from a 40 W fluorescent lamp);

c) The distance between the surface of the specimen and the naked eye is 350 mm.

The test of the thickness and mass of the plating shall be carried out in accordance with the provisions of GB/T 6463-2005 and the corresponding inspection methods, the results shall comply with the requirements of 4.10.

5.9 Biocompatibility

Check the relevant evidence of biocompatibility, which shall meet the requirements of 4.11. Otherwise the test is carried out as follows:

a) It is carried out according to the method as specified in GB/T 16886.5-2003, the results shall meet the requirements of 4.11 a);

b) It is carried out according to the method as specified in GB/T 16886.10-2005, the results shall meet the requirements of 4.11 b) and c).

5.10 Safety requirements for interconnection with medical electrical equipment

It is carried out according to the method as specified in Appendix A (Normative), the results shall comply with the requirements of 4.12.

5.11 Environmental test

It is tested according to the test sequence and test method in GB/T 14710-1993 as well as the requirements of 4.13, the results shall comply with the requirements of 4.13.

Appendix A

(Normative)

Safety requirements for interconnection with medical electrical equipment

A.1 Product characteristics

Hysteroscope is the BF-type application part of endoscopic electrical equipment.

A.2 External mark

A.2.1 Requirements

It shall have the following markings which are permanently adhered and clearly identifiable:

a) Corporate sign;

b) Product model or code.

A.2.2 Test methods

Use the method as specified in clause 6.1 of GB 9706.1-1995 to carry out inspection and test.

A.3 Completeness of accompanied file

A.3.1 Requirements

It shall comply with the provisions of 6.8.1 of GB 9706.1-1995.

A.3.2 Test methods

Check the accompanied file.

A.4 Instruction manual

A.4.1 Requirements

It shall comply with the provisions of 6.8.2 a) and d) of GB 9706.1-1995, meanwhile it shall comply with the provisions of 6.8.2 aa) and bb) of GB 9706.19-2000.

A.4.2 Test methods

electrical equipment, it has no requirement for this clause.

The wet pretreatment shall be carried out according to 4.10 in GB 9706.1-1995. The continuous leakage current test after wet pretreatment shall be carried out by the leakage current tester according to the provisions of 19.7 h) of GB 9706.1-1995. It is required to connect the matching cold light source for testing, the measurement circuit is as shown in Figure 21 and Appendix K of GB 9706.1-1995.

A.11 Dielectric strength after wet pretreatment

A.11.1 Requirements

According to the provisions of Table A.2, between the specified parts, it shall be able to withstand 50 Hz, sine wave and the specified test voltage for 1 min, without breakdown or flashover.

A.11.2 Test methods

The wet pretreatment is carried out according to 4.10 in GB 9706.1-1995. The dielectric strength test after wet pretreatment is carried out according to the provisions of 20.4 of GB 9706.1-1995, using the parameter tester of electric shock protection to test the medical electrical equipment.

A.12 Safety of face, corner, edge

A.12.1 Requirements

It shall meet the requirements of clause 23 of GB 9706.1-1995.

A.12.2 Test methods

Carry out visual observation and hand-touching inspection.

A.13 Protection of over-temperature hazard

A.13.1 Requirements

It shall meet the requirements of 42.3 in GB 9706.1-1995 and 42.3 in GB 9706.19-2000.

A.13.2 Test methods

It is carried out according to the method as specified in 42.3 of GB 9706.1-1995 and 42.3 of GB 9706.19-2000.

A.14 Cleaning, disinfection and sterilization

A.14.1 Requirements

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