YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0922-2014

Medical endoscopes - Endoscope accessories - Bridges

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1 Scope

YY/T 0922 is the product standard for the endoscope bridge, the coupling piece that joins a telescope to a sheath and provides the working channels through which instruments are passed, used above all in urology and hysteroscopy. It belongs to the Chinese series on endoscope accessories. A bridge is a mechanical interface with an optical consequence: it has to hold the telescope in exact alignment, seal against irrigation pressure, and let instruments pass without binding, while surviving the sterilisation cycles that every reusable endoscopic component goes through. For a manufacturer or an importer of rigid endoscope systems and their accessories for the Chinese market, this is the standard the bridge is specified and tested against.

This Standard specifies the terms, definitions, requirements and test methods of bridges. This Standard is applicable to bridges, which are used for endoscope import for medical purposes.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. In terms of references without a specified date, the latest version (including all the modifications) of is applicable to this Standard.

GB/T 14233.1-2008 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 14233.2-2005 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 2: Biological Test Methods

GB/T 16886.1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

YY/T 0149-2006 Medical Instruments of Stainless Steel - Test Methods of Corrosion Resistance

3 Terms and Definitions

The following terms and definitions are applicable to this Standard.

3.1 Endoscope Accessory Endoscope accessory refers to accessory, which are indispensable to and/or suitable for endoscope to implement the expected purposes of endoscope; or make it convenient for the implementation of the expected purposes of endoscope; or improve the expected purposes of endoscope; or increase the additional functions of endoscope. shall prevail in all the tests. In terms of materials which have already been proved to be applicable, if it can be proved that the subsequent manufacturing process of the materials would not generate biosafety hazards, repeated biological tests may be unnecessary. NOTE 1: in design, if instrument materials have demonstrable history of usage in specific application, or relevant material and/or instrument information may be obtained from other aspects, then, it may be believed that the materials have already been proved to be applicable before. NOTE 2: in terms of metal materials, if medical metal materials with an applicable range of application in national or industrial standards are adopted, repeated biological tests may be unnecessary.

4.2 Dimensions

4.2.1 Total length The nominal value tolerance of the total length of bridge shall be: ± 3% or 1 mm.

4.2.2 Minimum main channel width The minimum width of main channel shall be not less than the nominal value.

4.3 Coordination

4.3.1 Locking, inserting and disassembly Locking (if it is equipped with a locker), inserting and disassembly, which are jointly coordinated by bridge, sheath, endoscope or obturator, shall comply with the following requirements:

a) After the coordination, it shall be able to be locked; the locking shall be reliable;

b) Inserting shall be relaxing; disassembly shall be relaxing and convenient.

4.3.2 Positioning and sealing After the joint coordination of bridge, sheath or endoscope, it

shall satisfy the following requirements:

a) After it is properly inserted, the positioning shall be reliable; there shall be no loosening;

b) Except when the manufacturer claims that there is no requirement for sealing, after it is properly inserted, it shall be properly sealed. In water permeability test, within 1 min, permeated water shall not exceed 5 drops.

4.8.1 Sterility If bridges are disposable, they shall be sterile.

4.8.2 Ethylene oxide residue If the disposable bridges adopt ethylene oxide for sterilization, ethylene oxide residue shall be not more than 10 μg/g.

5.1 Materials

5.1.1 Chemical composition of metal materials Chemical composition of metal materials shall be tested through the method of appropriate precision.

5.1.2 Biocompatibility It is recommended that biological tests shall adopt relevant parts in GB/T 16886.

5.2 Dimensional Measurement

5.2.1 Equipment Standard measuring tools, measuring instruments or other tools with equivalent precision shall be adopted for measurement test.

5.2.2 Environmental conditions Room temperature: 23 °C ± 5 °C.

5.2.3 Procedure The procedure of measurement shall comply with routine methods.

5.3.1 Locking, inserting and disassembly test

5.3.1.1 Equipment Standard dynamometer or other equivalent tools.