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

中华人民共和国医药行业标准

YY 1028-2008
Replace YY 91028-1999

Upper gastro intestinal fiberscope
纤维上消化道内窥镜

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Foreword

This standard is in accordance with revision of YY 91028 - 1999 Upper gastro intestinal fiberscope by GB 11244 - 2005 General requirements for the medical endoscope and endoscope accessories.

This standard replaces YY 91028 - 1999 Upper gastro intestinal fiberscope.

This standard mainly differs from YY 91028-199 in that it adds the requirement of biological compatibility of touching body parts.

The electrical safety of this standard enforces GB 9706. 1 - 2007 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 environmental test of this standard excutes GB/T 14710 - 1993 The environmental requirements and test methods for medical electrical equipment.

The Appendix A of this standard is noamative.

This standard is put forward by and in the charge of Subcommittee on Medical Optics and Instrument of National Technical Committee on Optics and Optical Instruments of Standardization Administration (SAC/TC 103/SC 1).

This standard is drafted by Hangzhou Medical Equipment Quality Supervision&Inspection Center of State Drug Administration.

Main drafters of this part: Mao Xinxin, He Tao, Yan Qinglai, Jia Xiaohang, Ma Jun.

Upper Gastro Intestinal Fiberscope

This standard is the revision of YY 91028—1999 “Upper Gastro Intestinal Fiberscope” according to GB 1244—2005 “General Requirements for the Medical Endoscope and Endoscope Accessories”.

This standard replaces YY 91028—1999 “Upper Gastro Intestinal Fiberscope”.

Compared with YY 91028—1999, main difference of this standard is increasing biocompatibility requirements for the part contacting with human body.

Electrical safety of this standard compulsorily executes GB 9706.1—2007 “Medical Electrical Equipments — Part 1: General Requirements for Safety” and GB 9706.19—2000 “Medical Electrical Equipments—Part 2: Particular Requirements for the Safety of Endoscopic Equipment.

Environmental test of this standard executes GB/T 14710—1993 “Environmental Requirements and Test Method of Medical Electrical Equipment”.

Annex A to this standard is normative.

This standard is proposed by and under the jurisdiction of National Standardization Technical Committee of Optics and Optical Instruments Branch Technical Committee of Medical Optics and Instruments (SAC/TC 103/SC 1).

This standard is drafted by China Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center.

Main drafters of this part: Mao Xinxin, He Tao, Yan Qinglai, Jia Xiaohang, Ma Jun.

Upper Gastro Intestinal Fiberscope

1 Scope

This standard specifies upper gastro intestinal fiberscope classification, basic parameters, technical requirements, test method, inspection rules, marking, packaging, transportation and storage requirements.

This standard applies to upper gastro intestinal fiberscope series products, which are available for diagnosis or treatment of esophagus, stomach and duodenum.

2 Normative References

The following document is indispensable for the application of this document. For dated references, only dated edition applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 191-2008 Packaging - Pictorial marking for handling of goods

GB 9706.1-2007 Medical electrical equipment—Part 1: General requirements for safety

GB 9706.19-2000 Medical electrical equipment-Part 2: Particular requirements for the safety of endoscopic equipment

GB/T 16886.5-2003 Biological evaluation of medical devices--Part 5: Test for in vitro cytotoxicity

GB/T 16886.10-2005 Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity

GB/T 14233.1-1998 Infusion, transfusion, injection equipment for medical use--Part 1: Chemical analysis methods

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

3 Product classification

3.1 Upper gastro intestinal fiberscopes are divided into forward-looking type, squint-looking type and side-looking type.

3.2 Main parameters and boundary dimensions of upper gastro intestinal fiberscope shall conform to the provisions in table 1.

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