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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/T 0864-2011

Medical endoscopes-Endoscope functional supply units-Irrigation pump

医用内窥镜　内窥镜功能供给装置液体膨腔泵

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Contents

Foreword

This Standard is drafted according to the rules specified in GB/T 1.1-2009

Please note that some contents in this document may involve in the patent. The issuing authority of this document will not bear the responsibilities of these patents.

This Standard is proposed by China's State Food and Drug Administration.

This Standard is under the jurisdiction of National Technical Sub-committee (SAC/TC 103/ SC 1) on Medical Optical and Instrument of Standardization Administration of China.

The responsible drafting organizations are Hangzhou Medical Equipment Quality Supervision and Inspection Center of State Food and Drug Administration and Zhejiang Medical Equipment Inspection Center.

The chief drafting staff of this standard includes Yan Qinglai, Jia Xiaohang, He Tao, Qi Weiming Zhang Qinyuan and Zheng Jian.

Medical endoscopes-Endoscope functional supply units-Irrigation pump

1 Scope

This standard has stipulated the requirements for the liquid irrigation cavity pump (hereinafter referred to as the irrigation pump) used for medical endoscope.

This standard applies to irrigation pumps used in endoscope surgery. The products are used for the irrigation in the minimally invasive endoscope surgery.

2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

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 14233.2-2005 Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods

GB/T 14710-2009 Environmental requirement and test methods for medical electrical equipment

GB/T 16886.1-2011 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process

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

GB/T 16886.7-2001 Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals

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

YY 0709-2009 Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, tests and guidance for alarm systems

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