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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 0843-2011

**Medical endoscopes-Endoscope supply
units-Insufflators**

医用内窥镜 内窥镜功能供给装置 气腹机

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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.

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Medical endoscopes-Endoscope supply units-Insufflators

1 Scope

The Standard specifies the requirements and test methods of carbon dioxide insufflators for medical endoscope.

The Standard applies to the carbon dioxide insufflators used in the endoscopic surgery.

The product is used to establish and maintain the pneumoperitoneum in minimally invasive endoscopic 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

3 Requirements

3.1 Interface specifications

The type and connection thread of air suction interface between the insufflator and external air source shall comply with requirements in GB 15383-1994.

3.2 Air pressure

3.2.1 Set regulating range of air pressure

The manufacturer shall provide the regulating range of air pressure set which shall include 1999.5Pa (15mmHg) and be in compliance with the actual regulating range of air pressure set on the insufflator.

3.2.2 Accuracy on the presetting of air pressure

Tolerance of air pressure set is ± 266.6 Pa (2mmHg).

3.2.3 Accuracy on the display of air pressure

Tolerance of air pressure display is ± 266.6 Pa (2mmHg).