

ICS 11.040.70
C 40



PROFESSIONAL STANDARD OF THE PEOPLE'S
REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY/T 0283-2007
Replace YY/T 0283-1995

Large intestine fiber endoscope
纤维大肠内窥镜

Issued on July 02, 2007

Implemented on March 01, 2008

Issued by China Food and Drug Administration

Contents

Foreword	1
1 Scope	2
2 Normative references	2
3 Classification	3
4 Requirements	3
5 Test method	7
6 Inspection rule	13
7 Labeling and user manual	15
8 Package, transportation and storage	17
Annex A (Normative) Safety Requirements of the Connected Medical Electric Devices	18
Annex B (Normative) Illumination Tester	25
Annex C (Informative) Test Method of Dissolved Precipitate	26

Foreword

This standard is the revised edition of YY/T Q283-1995 “Large Intestine Fiber Endoscope”.

Compared with YY/T 0283-1995, this standard shows the following differences:

- Regulate the name of standard;
- Add the classification of waterproof ability of product
- Increase the quantity index of fractured fiber
- Add the requirements on illumination source and observation field;
- Modify the requirements on product label
- Add the requirements on waterproof product
- Add the requirements on biocompatibility
- Modify the test method of field angle;
- Cancel the requirements on air tightness in original standard
- Add annex A (Normative)

For electrical connection part, comply with GB 9706.1-1995 “Medical Electrical Equipment - Part 1: General Requirements for Safety”, GB 9706.4-1999 “Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment”, GB 9706.19-2000 “Medical Electrical Equipment-Part 2: Particular Requirements for the Safety of Endoscopic Equipment”. The details are given in annex A (Normative).

annex A and B of this standard is normative and annex C is informative.

This standard replaces YY/T 0283-1995 since the date of issuance.

This standard is approved by State Food and Drug Administration.

This standard is under jurisdiction of National Technical Committee on Medical Optical Instruments of Standardization Administration of China

This standard is drafted by Medical Equipment Factory of Shanghai Medical Instruments Co., Ltd.

The main drafters include Li Yafen, Sun Qi and Shen Tianming.

This standard was firstly published in November 1995.

Large Intestine Fiber Endoscope

1 Scope

This standard specifies the classification, labeling, requirements, test methods, inspection rules, identification, use manual, packaging, transportation and storage of large intestine fiber endoscope

This standard is applicable to large intestine fiber endoscope (hereinafter referred as fiber endoscope). This product is used to the examination and diagnosis of large intestine cavity and can also be used in the relevant surgical operation.

2 Normative references

The articles contained in the following documents have become this Standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 191-2008 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 9706.1-1995 Medical electrical equipment—Part 1: General requirements for safety

GB 9706.4-1999 Medical electrical equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment

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

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

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 (ISO 10993-10: 2002, IDT)

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

China Pharmacopeia of People's Republic of China, Edition 2005

Management Regulations on Medical Equipment Product Specifications, Labeling and Packaging Marking (Order 10, China's State Food and Drug Administration)

完整版本请在线下单/Order Checks Online for Full version

联系我们/or Contact:

TEL: 400-678-1309

QQ: 19315219 | Skype: Lancarver

Email : info@lancarver.com

<http://www.lancarver.com>

线下付款方式 :

I. 对公账户 :

单位名称 : 北京文心雕语翻译有限公司

开户行 : 中国工商银行北京学清路支行

账 号 : 0200 1486 0900 0006 131

II. 支付宝账户 : info@lancarver.com

III. Paypal: info@lancarver.com

注: 付款成功后, 请预留电邮, 完整版本将在一个工作日内通过电子 PDF 或 Word 形式发送至您的预留邮箱, 如需索取发票, 下单成功后的三个工作日内安排开具并寄出, 预祝合作愉快!

NOTE All documents on the store are in electronic Adobe Acrobat PDF format, there is not sell or ship documents in hard copy. Mail the order and payment information to info@lancarver.com, you will shortly receive an e-mail confirming your order.

