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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1298-2016

Medical endoscopes - Capsule endoscopes

医用内窥镜 胶囊式内窥镜

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Foreword

Chapter 5 of this standard is recommended and the remainder is mandatory. This standard is drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. The release of this document The Agency does not assume responsibility for identifying these patents. This standard is proposed by the State Food and Drug Administration. This standard is nationalized by the National Standardization Subcommittee for Medical Optics and Instruments (SAC/TC103/SC1). The standard drafting unit. Zhejiang Medical Devices Testing Institute, Anhan Optoelectronic Technology (Wuhan) Co., Ltd., Hangzhou, China Science and Technology Co., Ltd., Chongqing Jinshan Technology (Group) Co., Ltd. The main drafters of this standard. Jia Xiaohang, Zhang Qiaoyuan, Duan Xiaodong, Zhu Ziqiang, Li Xiangdong, Yan Qinglai, He Tao, Zheng Jian. Medical endoscopy capsule endoscope

1 Scope

YY/T 1298 is the Chinese standard for capsule endoscopes, the swallowable capsules that combine illumination, imaging and wireless transmission to photograph the digestive tract as they pass through it. They reach the small bowel, which conventional endoscopy cannot examine along its length, and they do it without sedation. The standard specifies the terms and definitions, the requirements, the test methods and the inspection rules, covering the materials in contact with the patient and their chemical composition, the optical performance including working distance and imaging quality, and the wireless transmission. The external image receiving and processing system is outside its scope, which is handled separately. Capsule endoscopy is manufactured in China at scale and exported widely. This is the document a Chinese registration is assessed against.

This standard specifies the requirements and definitions of capsular endoscopes, requirements, test methods, and inspection rules. This standard applies to capsule endoscopes.

Note. The capsule endoscope does not contain an external image receiving and processing

device or system.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document. Medical electrical equipment - Part 1. General requirements for safety

GB 9706.1 Medical electrical equipment - Part 2. Particular requirements for safety of endoscopic equipment GB 9706.19

GB/T 14233.1-2008 Methods of test for medical infusion, transfusion, and injectable utensils - Part 1. Chemical analysis methods

GB/T 14233.2 Methods of test for medical infusion, blood transfusion, and injectable utensils - Part 2. Biological test methods

GB/T 16886 (all parts) Biological evaluation of medical devices

YY 0068.1-2008 Medical endoscopic rigid endoscopes - Part 1. Optical properties and test methods

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Capsule endoscope A kind of capsule shape which is used in combination with an external image receiving and processing device or system for integrating illumination, imaging and wireless transmission. Endoscopy, mainly used to collect human digestive tract images.

3.2 Distal distal The optical axis of the capsule endoscope intersects the outer surface of the imaging direction.

3.3 Working distance workingdistance The distance between the observed object and the end of the capsule endoscope.

4.1 Materials used in contact with the patient

4.1.1 Chemical composition requirements The material used in contact with the patient should be given in any form possible. Where the metallic material shall indicate the grade and / Or the code and the chemical composition of the material requirements, the chemical composition of the metal material should be tested to verify.