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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0897-2013

Radiofrequency ablation equipment for ear, nose and throat

耳鼻喉射频消融设备

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. The standard electrical safety requirements for the implementation of the GB 9706.4-2009 "Medical electrical equipment - Part 2-2. High frequency surgery Equipment requirements for the safety "requirement, and GB 9706.4-2009 relevant provisions were amended and supplemented. Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents. As used in the form of material or structure is different from the equipment or components specified in this standard can prove that they achieve the same degree of safety, should be It is recognized. This standard was proposed by the China Food and Drug Administration. This standard by the National Technical Committee of Standardization for medical electrical physical therapy equipment at the Technical Committee (SAC/TC10/SC4) centralized. This standard was drafted. Tianjin, the State Food and Drug Administration Medical Device Quality Supervision and Inspection Center, Ahmed Medical Technology (Shanghai) Ltd., Olympus (Beijing) Sales Services Limited. The main drafters of this standard. Liu Bo, Qili Jing, Yang Juan, Zhang Yun, Wang Yuanjiang, Zhang Jie, Wang Cheng. ENT radiofrequency ablation device

1 Scope

YY 0897 is the mandatory Chinese standard for ENT radiofrequency ablation equipment, the low-temperature devices used to shrink turbinates, treat snoring and obstructive sleep apnoea, and remove tonsil and adenoid tissue. The attraction of the technique is that it works at temperatures well below conventional electrosurgery, causing less collateral damage and less postoperative pain in a region where swelling can obstruct the airway. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the radiofrequency output and its control, the electrode and the temperature at the treatment site, the cooling, and the protections against thermal injury beyond the target. Being a YY standard without the /T suffix, compliance is compulsory in

China.

This standard specifies the equipment Otolaryngology ablation terms and definitions, composition, requirements, test methods, inspection rules, marking, packaging, transportation Transport and storage.

3.1 This standard applies to the definition of ENT radiofrequency ablation device (hereinafter referred to as the device). This standard does not apply to high-frequency electrocautery device.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB/T 191 Packaging - Pictorial signs

GB 7543 single-use sterile rubber surgical gloves

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

GB 9706.4-2009 Medical electrical equipment - Part 2-2. requirements for the safety of high frequency surgical equipment

GB/T 14233.1 Infusion, transfusion, injection equipment - Part 1. Chemical analysis

GB/T 14233.2 Infusion, transfusion, injection equipment test methods - Part 2. Biological test methods

GB/T 14710 medical electrical environmental requirements and test methods

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation of the risk management process and Test

GB/T 16886.5 Biological evaluation of medical devices - Part 5. In vitro cytotoxicity tests

GB/T 16886.10 Biological evaluation of medical devices - Part 10. irritation and delayed-type hypersensitivity test Symbols - Part 1

YY/T 0466.1-2009 medical equipment used with medical device labels, labeling and information. General Claim

YY 0505 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and tests

YY 91057 medical foot switch General technical conditions

3 Terms and Definitions

GB 9706.1-2007 and GB 9706.4-2009 defined in the following terms and definitions apply to this document.

3.1 Including related accessories, including medical electrical equipment, it is expected to use ENT radiofrequency ablation electrode (hereinafter referred to as ablation electrode) the frequency of 200kHz ~ 5MHz of radio frequency energy to the site of submucosal ENT target tissues, its ablation.

3.2 ENT radiofrequency ablation electrode radio-frequencyablationelectrodeforear, noseandthroat And equipment used in conjunction to achieve the surgical ablation of accessory is expected to pierce the mucosa ENT site passing shot down its target tissues Frequency energy. NOTE. ENT radiofrequency ablation electrode may be a monopolar electrode, or a bipolar electrode.