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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0322-2018

Replacing YY 0322-2009

High frequency electrocautery therapy equipment

高频电灼治疗仪

Issued on: September 28, 2018 **Implemented on: April 1, 2020**

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Table of Contents

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 0322-2009 "High Frequency Electrocautery Therapy Apparatus". Compared with YY 0322-2009, except for editorial modifications The changes are as follows:

--- Revised the definition of high frequency electrocautery therapy device (see 3.1,

3.1 of.2009 edition);

--- Modified the output power requirements (see 5.2,.2009 version 4.2.2);

---Modified the requirements of the output indicating device (see 5.4,

4.2.4 of the.2009 edition);

--- Increased standby noise, random file requirements (see 5.5, 5.8);

---Modified the requirements for electromagnetic compatibility (see 5.11,

4.4 of the.2009 edition);

--- Removed the definition of load impedance and output (3.2,

3.3 of.2009 edition);

--- Removed the requirements of the output controller (2009 version 4.2.5). Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying these patents. This standard was proposed by the State Drug Administration. This standard is under the jurisdiction of the National Medical Electrical Equipment Standardization Technical Committee Physical Therapy Equipment Subcommittee (SAC/TC10/SC4). This standard was drafted. Tianjin Medical Device Quality Supervision and Inspection Center. The main drafters of this standard. Liu Bo, Li Yanan, Qi Lijing, Han Mo, Ji Caiyan, Wu Gang. The previous versions of this standard were released as follows:

---YY 0322-2000, YY 0322-2009. High frequency electrocautery therapeutic apparatus

1 Scope

YY 0322 is the mandatory Chinese standard for high frequency electrocautery therapy equipment, the devices that destroy small lesions by passing high frequency current through a probe. They are used in dermatology, gynaecology and ENT outpatient clinics for warts, polyps and cervical treatment. This document sets the requirements such equipment has to meet and the test methods that verify them, covering the high frequency output and its control, the electrode, the leakage currents that could take an unintended path through the patient, and the protections against burns at the return electrode or at incidental contact points. Being a YY standard without the /T suffix, compliance is compulsory in China. It replaces YY 0322-2009 and carries Amendment 1 of 2023.

This standard specifies the terms and definitions, composition, requirements, and test methods of the high frequency electrocautery therapeutic apparatus. This standard applies to the high frequency electrocautery treatment instrument defined in 3.1 (hereinafter referred to as the therapeutic device).

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article. Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety (IEC 60601-1.1988, IDT)

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

IEC 60601-2-2. 2006, IDT)

GB 9706.15-2008 Medical electrical equipment - Part 1-1. Safety common requirements Parallel standard. Safety of medical electrical systems Seeking (IEC 60601-1-1.2000, IDT)

GB/T 14710-2009 Environmental requirements and test methods for medical appliances

GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management (ISO 10993-1.2009, IDT)

YY 0505-2012 Medical electrical equipment - Part 1-2. Safety common requirements Parallel standard. Electromagnetic compatibility requirements and testing (IEC 60601-1-2.2004, IDT)

YY 1057 medical foot switch general technical conditions

3 Terms and definitions

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

3.1 Unipolar HF surgical equipment with a rated output power not exceeding 50 W and intended without neutral electrodes.

4 Composition

The high frequency electrocautery treatment device is usually composed of a host computer, a surgical accessory, a foot switch, and the like.

5 Requirements

5.1 Working frequency The operating frequency error should not exceed ±10% of the nominal value.

5.2 rated output power The rated output of the therapy device should not exceed 50W and the error should not exceed ±20% of the nominal value.