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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0322-2018

**High frequency electrocautery therapy equipment
(English Translation)**

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Foreword

This standard is 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, the main technical the changes are as follows:

- Modified the definition of high-frequency electrocautery therapeutic apparatus (see 3.1, 3:1 of the:2009 edition);
- Modified the requirements for output power (see 5.2, 4:2:2 of the:2009 edition);
- Modified the requirements for 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);
- Deleted the definition of load impedance and output (3:2, 3:3 of the:2009 edition);
- Deleted the output controller requirements (4:2:5 of the:2009 edition):

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by the State Drug Administration:

This standard is under the jurisdiction of the Physical Therapy Equipment Sub-Technical Committee (SAC/TC10/SC4) of the National Medical Electrical Appliances Standardization Technical Committee:

This standard was drafted: Tianjin Medical Device Quality Supervision and Inspection Center:

1 Scope

This standard specifies the terms and definitions, components, requirements, and test methods of high-frequency electrocautery therapeutic apparatus:

This standard applies to the high-frequency electrocautery therapeutic apparatus (hereinafter referred to as therapeutic apparatus) defined in 3:1:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB 9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements (IEC 60601-1:1988, IDT) GB 9706.4-2009 Medical Electrical Equipment Part 2-2: Special Requirements for Safety of High Frequency Surgical Equipment (IEC 60601-2-2: 2006, IDT)

GB 9706.15-2008 Medical Electrical Equipment Part 1-1: General Safety Requirements Collateral Standard: Safety Requirements for Medical Electrical Systems Seek (IEC 60601-1-1:2000, IDT) GB/T 14710-2009 Environmental requirements and test methods for medical electrical appliances GB/T 16886.1-2011 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (ISO 10993-1:2009, IDT) YY 0505-2012 Medical Electrical Equipment Part 1-2: General Safety Requirements Collateral Standard: Electromagnetic Compatibility Requirements and Tests (IEC 60601-1-2:2004, IDT) YY 1057 General Technical Specifications for Medical Foot Switches

3 Terms and Definitions

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

Monopolar high-frequency surgical equipment with a rated output power not exceeding 50W and intended for use without a neutral electrode:

4 Components

The high-frequency electrocautery treatment instrument is usually composed of a host, surgical accessories, foot switches, etc:

5 Requirements

5.1

Operating frequency the operating frequency error should not exceed $\pm 10\%$ of the nominal value:

5.2

Rated output power the rated output power of the therapeutic device should not exceed 50W, and the error should not exceed $\pm 20\%$ of the nominal value:

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