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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0776-2023

Replacing YY/T 0776-2010

Liver radiofrequency ablation therapy equipment

肝脏射频消融治疗设备

Issued on: June 20, 2023 **Implemented on: July 1, 2025**

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. This document replaces YY 0776-2010 "Liver radiofrequency ablation treatment equipment". Compared with YY 0776-2010, except for structural adjustment and compilation In addition to editorial changes, the main technical changes are as follows:

---Changed the definitions of liver radiofrequency ablation treatment equipment and liver radiofrequency ablation electrodes (see 3.1, 3.2,.2010 version of 3.1, 3.2);

---Added terms and definitions for water-cooled liver radiofrequency ablation electrodes and auxiliary (remote) temperature probes (see 3.3, 3.4);

---Changed the requirements for operating frequency and rated output power (see 4.2, 4.3, 5.2.1,

5.2.2 of the.2010 edition);

---Added requirements for high current mode (see 4.4);

---Changed the requirements for temperature display function, impedance display function, protection function and timing function (see 4.5, 4.6, 4.7, 4.8,.2010 Versions 5.2.3, 5.2.5, 5.2.7, 5.2.6);

---Added requirements for perfusion pumps (see 4.9);

---Changed the requirements for foot switches (see 4.10,

5.5 of the.2010 version);

---Added requirements for size, DC resistance, insulation resistance, Luer connector, and corrosion resistance (see 4.11.1, 4.11.2, 4.11.3, 4.11.6);

---Changed the requirements for neutral electrode, environmental testing, safety, and

electromagnetic compatibility (see 4.12, 4.13, 4.14, 4.15,.2010 edition 5.4, 5.8, 5.6, 5.7);

---Deleted biocompatibility, temperature control range and error, minimum area, and additional requirements for instructions for use (see the.2010 version of 5.3.1, 5.4.1, 5.2.4, 5.4.2, 5.9). Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the Physical Therapy Equipment Sub-Technical Committee of the National Medical Electrical Standardization Technical Committee (SAC/TC10/SC4). This document was drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, Med Medical Technology (Shanghai) Co., Ltd. The main drafters of this document. Liu Bo, Yang Jiangang, Zhang Longfei, Li Yanan, Hou Feixiang, and Lu Suyang. The previous versions of the documents replaced by this document are as follows:

1 Scope

YY/T 0776 covers the equipment used for radiofrequency ablation of liver tumours, the generator and electrode that destroy a lesion with heat delivered through a needle rather than by resection. It 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 ablation zone it produces, the temperature and impedance monitoring that governs the treatment, and the safety systems that limit damage to surrounding tissue. Ablation is the standard of care for small hepatocellular carcinomas in patients who cannot undergo surgery, and liver cancer is one of the most common cancers in China. The 2023 edition replaces YY/T 0776-2010. For a manufacturer, this is the product-specific text a Chinese registration is judged against.

This document specifies the requirements and test methods for liver radiofrequency ablation therapy equipment (hereinafter referred to as "equipment") and its accessories. This document applies to liver radiofrequency ablation treatment equipment and its accessories.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 1962.2 Syringes, injection needles and other medical devices 6% (Luer) conical connectors Part

3 Terms and definitions

The following terms and definitions as defined in GB 9706.1 and GB 9706.202-2021 apply to this document.

3.1 It is expected to be used in conjunction with liver radiofrequency ablation electrodes and other accessories to use high-frequency current to ablate liver solid tumors. technical equipment.

3.2 A surgical accessory used in conjunction with liver radiofrequency ablation treatment equipment. The electrode tip is usually passed through the skin under the guidance of imaging equipment such as ultrasound. The puncture operation reaches the liver target tissue, and the high-frequency current generated by the device is transmitted to the target tissue for ablation treatment.

Note. Liver radiofrequency ablation electrodes can contain temperature sensors, such as thermocouples, thermistors, etc.

3.3 The liver radiofrequency ablation electrode is used in conjunction with the perfusion pump. Driven by the perfusion pump, the cooling liquid flows through the electrode, counter electrode and adjacent tissue. Cool down to prevent carbonization and increase the ablation area.