

CCS C42

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

YY 0838-2021

Microwave ablation and coagulation equipment

微波热凝设备

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Foreword

All technical content of this standard is mandatory. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 0838-2011 "Microwave Thermocoagulation Equipment". Compared with YY 0838-2011, the main technology except for editorial changes The changes are as follows:

---Modified the definitions of the terms microwave thermocoagulation equipment and fuser (see 3.1, 3.2, 3.1,

3.3 of the.2011 edition);

---Added the definitions of the terms superficial tissue thermocoagulation equipment, internal tissue thermocoagulation equipment, and prostate thermocoagulation equipment (see 3.3~3.5);

--- Added the definition of superficial tissue thermocoagulator (see 3.6);

---Modified the content of composition and classification (see Chapter 4, Chapter 4 of the.2011 edition);

---Modified the requirements and test methods for working frequency, output power, timing, power adjustment (see 5.2~5.5, 6.2~6.5,.2011 Version 5.2~5.5, 6.2~6.5);

---Added no-load protection requirements and test methods (see 5.6, 6.6);

---Modified the requirements and test methods for the surface temperature of the fuser (see 5.7, 6.7, 5.9,

6.9 in the.2011 edition);

---Added cooling system requirements and test methods (see 5.8, 6.8);

---The requirements and test methods for tissue temperature measurement, tissue temperature control, and over-temperature protection have been revised (see 5.9~5.11, 6.9~6.11,.2011 edition 5.6~5.8, 6.6~6.8);

---Added the adaptation function, multi-source output power requirements and test methods (5.12, 5.13, 6.12, 6.13);

---Modified the requirements and test methods of the instruction manual (see 5.14, 6.14, 5.12.5,

1 Scope

YY 0838 is the mandatory Chinese standard for microwave ablation and coagulation equipment, the systems that destroy tumours by heating them with a microwave antenna placed in the lesion. Microwave ablation has largely displaced radiofrequency for liver and lung tumours in Chinese practice because it heats faster, reaches higher temperatures and is less affected by the cooling effect of nearby blood vessels. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering the microwave output and its control, the antenna and the ablation zone it produces, the cooling of the shaft that prevents burns along the insertion track, and the monitoring. It replaces YY 0838-2011 and took effect in May 2023.

6. Specific requirements for the basic safety and basic performance of microwave therapy equipment

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article. For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 9706.1 Medical electrical equipment Part

GB 9706.206 Medical electrical equipment Part 2-

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

GB/T 16886.1 Biological Evaluation of Medical Devices Part

3 Terms and definitions

The following terms and definitions defined in GB 9706.1, GB 9706.206 and YY 0899 apply to this document.

3.1 Use a contact applicator to transmit an electromagnetic field with a frequency greater than 300MHz but not more than 30GHz in the tissue, so that the patient's local tissue Microwave treatment equipment that produces coagulation/ablation.

3.2 Ablation/coagulation applicator A contact applicator that transmits microwave energy in local tissues and coagulates/ablates the tissues.

3.3 Superficial organization ablation/coagulation equipment Microwave thermocoagulation

equipment used for superficial skin or open cavity can be directly visualized to coagulate hyperplasia and diseased tissues.

3.4 In vivo tissue thermocoagulation equipment

intracorporal organization ablation/coagulation equipment Under the guidance of auxiliary equipment such as imaging, microwave heat is used for coagulation/ablation treatment of intracorporeal or non-visual cavity hyperplasia and diseased tissues. Coagulation equipment.

3.5 Prostate ablation/coagulation equipment A microwave thermal coagulation device for coagulation/ablation of benign prostatic hyperplasia tissue by using a prostate thermal coagulator.