

ICS 11.040.60

CCS C42

YY

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

YY 0839-2011

Microwave hyperthermia equipment

微波热疗设备

Issued on: December 31, 2011

Implemented on: June 1, 2013

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Classification and composition

Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. Microwave hyperthermia equipment is a use of microwave heating of the tissue penetration of hyperthermia equipment. In order to standardize the technology and special products , To ensure safety and efficacy, formulated industry standards, as a basis for production and quality control of products. The standard safety requirements for full implementation of the GB 9706.1-2007 "Medical Electrical Equipment Part 1. General requirements for safety," the Provisions. This revised standard adopts GB 9706.6-2007 "Medical electrical equipment Part 2. requirements for the safety of microwave therapy equipment," the Provisions. The standards for electromagnetic compatibility requirements in accordance with YY 0505-2005 "Medical electrical equipment - Part 1-2. General requirements for safety tie Standard. EMC requirements and tests "to run concurrently. 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. If the requested material or structure in the form of equipment or components used in connection with the standards required by different, but if they can prove that it reaches the same Requirements, which should be recognized. This standard was proposed by the State Food and Drug Administration. This standard by the national standardization of physical therapy equipment Medical Electrical Technical Committee of Standardization Technical Committee (SAC/TC10/SC4) Centralized. This standard was drafted. Tianjin, the State Food and Drug Administration Medical Device Quality Supervision and Inspection Center, Xuzhou LEVANTINA medical equipment Limited. The main drafters of this standard. Yang Juan, Qili Jing, Han desert, Liu Bo, Wu Gang. Microwave hyperthermia equipment

1 Scope

YY 0839 is the mandatory Chinese standard for microwave hyperthermia equipment, the devices that raise the temperature of tumour tissue with microwave energy as an adjunct to radiotherapy or chemotherapy. Hyperthermia works by holding tissue in a narrow therapeutic temperature band: too low and there is no sensitising effect, too high and it becomes ablation. 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 applicators, the temperature monitoring the treatment is steered by, and the protection of tissue outside the target. It sits alongside YY 0838 on microwave ablation, which uses the same physics for a different purpose. Being a YY standard without the /T suffix, compliance is compulsory.

This standard specifies the terms and definitions microwave hyperthermia equipment, classification and composition requirements, test methods, inspection rules, marking, packaging, transport Transport and storage.

3.1 This standard applies to the definition of microwave hyperthermia device (hereinafter referred to as hyperthermia equipment), the hyperthermia device has a temperature measurement and control functions for Clinical tumor adjuvant therapy.

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 191-2008 Packaging - Pictorial signs

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

GB 9706.6-2007 Medical electrical equipment Part 2. requirements for the safety of microwave therapy equipment

GB 9706.15-2008 Medical electrical equipment - Part 1-1. General requirements for safety Collateral standard. medical electrical systems security Claim

GB/T 14710-2009 medical electrical environmental requirements and test methods Biological evaluation of

GB/T 16886 (all parts) Medical Devices

YY 0505-2005 Medical electrical equipment - Part 1-2. General requirements for safety Collateral standard. Electromagnetic compatibility requirements and tests

3 Terms and Definitions

GB 9706.1-2007 and GB 9706.6-2007 defined in the following terms and definitions apply to this document.

3.1 Use the operating frequency of 0.3GHz ~ 30GHz microwave source, the microwave energy propagation through the radiator and having a temperature measurement and control functions for Therapy equipment neoplastic disease.

4 Classification and composition

4.1 Classification Divided by the temperature measurement methods. continuous and intermittent temperature shutdown temperature. Intervention by temperature divided into. lossy and lossless temperature measurement temperature. Press temperature Divided into. start/stop temperature control and adaptive power output temperature.

4.2 Composition Hyperthermia equipment from the microwave source, radiators, couch (if applicable), temperature measurement and control system and other control system functions.