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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.262-2021

Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

医用电气设备 第2-62部分：高强度超声治疗(HITU)设备的基本安全和基本性能专用要求

Issued on: March 9, 2021 **Implemented on: May 1, 2023**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 9 March 2021 by the National Medical Products Administration and takes effect on 1 May 2023.

It is a YY standard without the /T suffix: compliance is mandatory in China.

All the technical contents of this Part are mandatory. Medical Electrical Equipment serial standards are divided into two parts.

--- Part 1: General and Collateral Requirements;

--- Part 2: Particular Requirements. This Part is Part 2-62. This Part was drafted as per the rules specified in GB/T 1.1-2009. This Part uses the redrafting method to modify and adopt

IEC 60601-2-62.2013 Medial Electrical Equipment - Part 2-62: Particular Requirements for the Basic Safety and Essential Performance of High Intensity Therapeutic Ultrasound (HITU) Equipment. The technical differences and the causes between this Part and IEC 60601-2-62.2013 are as follows.

--- Regarding Normative References, this Part has made adjustments with technical differences to adapt to the technical conditions of China. The adjustments are concentrated in Clause 2, "Normative References". The specific adjustments are as follows. ? Use YY/T 0642 that equivalently adopts the international standard to replace IEC 62359 (see 201.2); ? Use YY/T 0750-2018 that modifies and adopts the international standard to replace IEC 61689.2013 (see 201.2); ? Use YY/T 0865.1 that equivalently adopts the international standard to replace IEC 62127-1 (see 201.2); ? Use YY/T 0865.2 that equivalently adopts the international standard to replace IEC 62127-2 (see 201.2). This Part made the following editorial modifications as follows.

--- Deleted the content of reference [3-10] mentioned in the NOTE of the Normative References;

--- According to the numbering rules for annexes in the text of the Standard, modify Annex A to Annex AA;

--- According to the numbering rules for annexes in the text of the Standard, modify Annex D to Annex DD;

--- Add some NOTE to this Part. Please note some contents of this Document may involve patents. The issuing agency of this Document shall not assume the responsibility to identify these patents. This Part was proposed by National Medical Products Administration. This Part shall be under the jurisdiction of Subcommittee of Medical Ultrasound Equipment of National Technical Committee on Medical Electrical Equipment of Standardization Administration of China (SAC/TC 10/SC 2). Drafting organizations of this Part. Hubei Institute of Medical Device Quality Supervision and Testing; Chongqing Haifu Medical Technology Co., Ltd.; and Wuxi Haiying Electronic Medical System Co., Ltd. Chief drafting staffs of this Part. Jiang Shilin, Ye Fangwei, Wang Guoying, and Xu Yang. 201.1 Scope, Object and Collateral Standards Clause 1 of the general standard applies, except as follows. 201.2 Normative References Clause 2 of the general standard applies, except as follows: Replacement. 201.3 Terms and Definitions For the purposes of this Document, the terms and definitions given in GB 9706.1, YY/T 0642, YY/T 0865.1 and YY/T 0750 and the following apply. 201.4.11 POWER INPUT Addition. This clause of the general standard applies with EQUIPMENT operated at maximum OUTPUT POWER. 201.5 General Requirements for Testing of ME EQUIPMENT Clause 5 of the general standard applies, except as follows. 201.6 Classification of ME EQUIPMENT and ME SYSTEMS Clause 6 of the general standard applies. 201.7 ME EQUIPMENT Identification, Marking and Documents Clause 7 of the general standard applies, except as follows: Addition. 201.8 Protection against Electrical HAZARDS from ME EQUIPMENT Clause 8 of the general

standard applies, except as follows. 201.9 Protection against Mechanical Hazards of ME EQUIPMENT and ME SYSTEMS Clause 9 of the general standard applies. 201.10 Protection against Unwanted and Excessive Radiation HAZARDS Clause 10 of the general standard applies, except as follows. 201.11 Protection against excessive temperatures and other HAZARDS Clause 11 of the general standard applies, except as follows. 201.12 Accuracy of controls and instruments and protection against hazardous outputs Clause 12 of the general standard applies, except as follows. 201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT Addition. 201.14 Programmable ELECTRICAL MEDICAL SYSTEMS (PEMS) Clause 14 of the general standard applies 201.15 Construction of ME EQUIPMENT Clause 15 of the general standard applies 201.16 ME systems Clause 16 of the general standard applies 201.17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS Clause 17 of the general standard applies except as follows: Addition.

1 Scope

YY 9706.262 is the mandatory Chinese standard for high intensity therapeutic ultrasound equipment, the systems that ablate tissue by focusing ultrasound to a point deep in the body without an incision. HIFU is used in China for uterine fibroids, for liver and pancreatic tumours and in some neurological applications, and Chinese manufacturers are among the world leaders in it. The standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the acoustic output and its characterisation, the accuracy with which the focus is placed, the treatment monitoring, and the protections against depositing energy outside the intended volume. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.

202 Electromagnetic Compatibility - Requirements and Tests

YY 9706.102 applies, except as follows. .....