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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.102-2021

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

医用电气设备 第1-2部分：基本安全和基本性能的通用要求 并列标准：电磁兼容要求和试验

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Foreword

All the technical contents in this Part are mandatory. Medical Electrical Equipment can be divided into the following two parts.

1.General and Collateral Requirements;

2.Particular Requirements. This Part is Part 1-2. This Part was drafted as per the rules specified in GB/T 1.1-2009. This Part replaced YY 0505-2012 Medical Electrical Equipment - Part 1-

2.General Requirements for Safety - Collateral Standards. Electromagnetic Compatibility - Requirements and Tests. Compared with YY 0505-2012, the major technical differences of this Part are as follows:

--- Medical electrical equipment and medical electrical system are referred to as ME equipment and ME system;

--- Add some terms and definitions (see Clause 3 of this Edition);

--- Delete GB 9706.15-2008 (see Clause 2 of the 2012 Edition);

--- Update the year number or standard number of some standards (see Clause 2 of this Edition);

--- Add annexes on marking and labelling guidelines and etc. (see Annex B). This Part uses

re-drafting method to modify and adopt IEC 60601-1-2.2007 Medical Electrical Equipment - Part 1-

2.General Requirements for Basic Safety and Essential Performance - Collateral Standard. Electromagnetic Compatibility - Requirements and Tests. The technical differences and the causes between this Part and IEC 60601-1-2.2007 are as follows:

--- Regarding normative references, this Part has made adjustments with technical differences to adapt to China's technical conditions. The adjustments are reflected in Clause

2 Normative References. The specific adjustments are as follows: Replace the international standard CISPR 14-1 by GB 4343.1 which equivalently adopts the international standard; Replace the international standard CISPR 11 by GB 4824 which equivalently adopts the international standard; Replace the international standard IEC 60417 by GB/T 5465.2-2008 which equivalently adopts the international standard; Replace the international standard CISPR 16-1-2 by GB/T 6113.102 which equivalently adopts the international standard; Replace the international standard CISPR 22 by GB/T 9254 which equivalently adopts the international standard; Replace the international standard IEC 60601-1.2005 by GB 9706.1-2020 which equivalently adopts the international standard; Replace the international standard IEC 61000-3-2 by GB 17625.1 which equivalently adopts the international standard; Replace the international standard IEC 61000-3-3 by GB/T 17625.2 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-2 by GB/T 17626.2 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-3 by GB/T 17626.3 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-4 by GB/T 17626.4-2018 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-5 by GB/T 17626.5 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-6.2006 by GB/T 17626.6- 2017 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-8 by GB/T 17626.8 which equivalently adopts the international standard; Replace the international standard IEC 61000-4-11 by GB/T 17626.11 which equivalently adopts the international standard; Replace the international standard CISPR 15 by GB/T 17743 which equivalently adopts the international standard; Replaced the international standard IEC 60601-1-8.2006 by YY 9706.108- 2021 which modifies and adopts the international standard. This Part also made the following editorial modifications.

--- Modify some arrangement formats according to GB/T 1.1-2009. 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 State Food and Drug Administration. This Part shall be under the jurisdiction of National Technical Committee on Medical Electrical Equipment of Standardization Administration (SAC/TC

10). The historical editions replaced by this Part are as follows:

--- YY 0505-2005, YY 0505-2012.

1 Scope, Object and Related Standards

YY 9706.102 is the electromagnetic compatibility collateral standard for medical electrical equipment, and it applies to essentially every powered medical device sold in China. It sets what a device must tolerate without losing its essential performance and what it may emit, covering immunity to radiated and conducted fields, electrostatic discharge, surges and supply interruptions, and the emission limits that keep one device from disturbing another. Hospitals are dense electromagnetic environments and are getting denser as wireless equipment proliferates, so this is one of the most frequently cited documents in any Chinese registration dossier. At more than forty thousand words it is the largest of the collateral standards. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.

This Part applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this document.

GB 4343.1 Electromagnetic Compatibility Requirements for Household Appliances, Electric Tools and Similar Apparatus - Part

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in GB 9706.1-2020, YY 9706.108-2021 and the following definitions apply. 3.1 (IMMUNITY) COMPLIANCE LEVEL Level less than or equal to the IMMUNITY LEVEL for which the ME EQUIPMENT or ME SYSTEM meets the requirements of the applicable subclause of 6.2. 3.2 * DEGRADATION (of performance) Undesired departure in the operational performance of ME EQUIPMENT or an ME SYSTEM from its intended performance.

4 General Requirements

ME EQUIPMENT and ME SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment or the ESSENTIAL PERFORMANCE of other ME EQUIPMENT and ME SYSTEMS. ME EQUIPMENT and ME

SYSTEMS shall have adequate IMMUNITY to be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of ELECTROMAGNETIC DISTURBANCES. For EMC testing, the SINGLE FAULT CONDITION requirements of the general standard do not apply.

5 Identification, Marking and Documents

ME EQUIPMENT and ME SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labelled with symbol 5140 in GB/T 5465.2-2008 for non-ionizing radiation.