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PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 9706.102-2021

Replacing YY 0505-2012

**Medical Electrical Equipment - Part 1-2: General
Requirements for Basic Safety and Essential Performance
- Collateral Standard: Electromagnetic Compatibility -
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
(IEC 60601-1-2:2007, MOD)

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Table of Contents

Foreword.....	3
Introduction	6
1 Scope, Object and Related Standards.....	9
2 Normative References	10
3 Terms and Definitions	11
4 General Requirements.....	16
5 Identification, Marking and Documents	17
6 Electromagnetic Compatibility.....	41
Annex A (Informative) General Guidance and Rationale.....	66
Annex B (Informative) Guide to Marking and Labelling Requirements for ME EQUIPMENT and ME SYSTEMS	102
Annex C (Informative) Example completion of Table 1 through Table 8.....	104
Annex D (Informative) Guidance in classification according to GB 4824	114
Annex E (Informative) Guidance in the application of particular standards..	118
Annex F (Informative) ELECTROMAGNETIC ENVIRONMENTS	122
Annex G (Informative) Guidance for determining if electrical equipment that is not ME EQUIPMENT and that is used in an ME SYSTEM is exempt from the EMC testing requirements of this Part	123
Annex H (Informative) Mapping between the elements of YY 0505-2012 and this Part.....	125

Foreword

All the technical contents in this Part are mandatory.

Medical Electrical Equipment can be divided into the following two parts:

- Part 1: General and Collateral Requirements;
- Part 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.

Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

1 Scope, Object and Related Standards

1.1 * Scope

This Part applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This Part applies to ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS.

NOTE: The clauses and articles with an asterisk (*) in this Part are explained in Annex A.

1.2 Object

The object of this Part is to specify general requirements and tests for ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 GB 9706.1

For ME EQUIPMENT and ME SYSTEMS, this Part complements GB 9706.1.

When referring to GB 9706.1 or to this Part, either individually or in combination, the following conventions are used:

- "the general standard" designates GB 9706.1 alone;
- "this Part" designates YY 9706.102 alone;
- "this Standard" designates the combination of the general standard and this Part.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this Part.

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 1: Emission (GB 4343.1-2018, CISPR 14-1:2011, IDT)

GB 4824 Industrial, Scientific and Medical Equipment - Radio-frequency Disturbance Characteristics - Limits and Methods of Measurement (GB 4824-2013, CISPR 11:2010, IDT)

GB/T 5465.2-2008 Graphical Symbols for Use on Electrical Equipment - Part 2: Graphical Symbols (IEC 60417 DB:2007, IDT)

GB/T 6113.102 Specification for Radio Disturbance and Immunity Measuring Apparatus and Methods - Part 1-2: Radio Disturbance and Immunity Measuring Apparatus - Coupling Devices for Conducted Disturbance Measurements (GB/T 6113.102-2018, CISPR 16-1-2:2014, IDT)

GB/T 9254 Information Technology Equipment - Radio Disturbance Characteristics - Limits and Methods of Measurement (GB/T 9254-2008, CISPR 22:2006, IDT)

GB 9706.1-2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2012, MOD)

GB 17625.1 Electromagnetic Compatibility – Limits - Limits for Harmonic Current Emissions (Equipment Input Current ≤ 16 A Per Phase) (GB 17625.1-2012, IEC 61000-3-2:2009, IDT)

GB/T 17625.2 Electromagnetic Compatibility (EMC) – Limits - Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment With Rated Current ≤ 16 A Per Phase (GB/T 17625.2-2007, IEC 61000-3-3:2005, IDT)

GB/T 17626.2 Electromagnetic Compatibility - Testing and Measurement Techniques -Electrostatic Discharge Immunity Test (GB/T 17626.2-2018, IEC

61000-4-2:2008, IDT)

GB/T 17626.3 Electromagnetic Compatibility - Testing and Measurement Techniques – Radiated, Radio-Frequency, Electromagnetic Field Immunity Test (GB/T 17626.3-2016, IEC 61000-4-3:2010, IDT)

GB/T 17626.4-2018 Electromagnetic Compatibility - Testing and Measurement Techniques - Electrical Fast Transient/Burst Immunity Test (IEC 61000-4-4, 2012, IDT)

GB/T 17626.5 Electromagnetic Compatibility - Testing and Measurement Techniques - Surge Immunity Test (GB/T 17626.5-2008, IEC 61000-4-5:2014, IDT)

GB/T 17626.6-2017 Electromagnetic Compatibility - Testing and Measurement Techniques - Immunity to Conducted Disturbances, Induced by Radio-Frequency Fields (IEC 61000-4-6:2013, IDT)

GB/T 17626.8 Electromagnetic Compatibility (EMC) - Part 8: Testing and Measurement Techniques - Power Frequency Magnetic Field Immunity Test (GB/T 17626.8-2006, IEC 61000-4-8:2001, IDT)

GB/T 17626.11 Electromagnetic Compatibility - Testing and Measurement Techniques - Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests (GB/T 17626.11-2008, IEC 61000-4-11:2004, IDT)

GB/T 17743 Limits and Methods of Measurement of Radio Disturbance Characteristics of Electrical Lighting and Similar Equipment (GB/T 17743-2017, CISPR 15:2015, IDT)

YY 9706.108-2021 Medical Electrical Equipment - Part 1-8: General Requirements for Basic Safety and Essential Performance - Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems (IEC 60601-1-8:2012, MOD)

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.

NOTE 1: Where the terms “voltage” and “current” are used in this Part, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2: The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This Part also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

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