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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.111-2021

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

医用电气设备 第1-11部分：基本安全和基本性能的通用要求 并列标准：在家庭护理环境中使用的医用电气设备和医用电气系统的要求

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

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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 technical contents (requirements) in this part are mandatory. The series of standards, Medical electrical equipment, include two parts.

-- Part 1: General and collateral requirements;

-- Part 2: Particular requirements.

This part is Part 1-11. This part was drafted in accordance with the rules given in GB/T 1.1-2009. This part was redrafted and modified in relation to IEC 60601-1-11.2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard. Requirements for medical electrical equipment and

medical electrical systems used in the home healthcare environment. The technical differences between this part and IEC 60601-1-11.2015 and their reasons are as follows.

-- Regarding normative references, adjustments with technical differences were made in this part to adapt to Chinese technical conditions.

The adjustments are reflected in Chapter 2 "Normative references". The specific adjustments are as follows. ? CISPR 11.2009 is replaced with GB 4824, which is identical to the international standard; ? IEC 60601-1.2005+AMD1.2012 is replaced with GB 9706.1, which is modified in relation to the international standard; ? IEC 60601-1-2.2014 is replaced with YY 9706.102, which is modified in relation to the international standard; ? IEC 60601-1-6.2010+AMD1.2013 is replaced with YY/T 9706.106, which is modified in relation to the international standard; ? IEC 60601-1-8.2006+AMD1.2012 is replaced with YY 9706.108-2021, which is modified in relation to the international standard; ? IEC 60601-1-12.2014 is replaced with YY 9706.112, which is modified in relation to the international standard;

-- The 8-year education specified in IEC 60601-1-11.2015 is modified into the Chinese 9-year compulsory education (see 7.1);

-- The requirement "if indication marks for the control of ME EQUIPMENT are explained in text, they shall be in Chinese" is Added (see 7.1).

The following editorial changes are made to this part.

-- A.3 is added to Appendix A to provide the corresponding relationship between international standards and current Chinese national standards or industry standards;

-- The index is deleted. Please note that some content in this document may be subject to patents.

The publisher of this document assumes no responsibility for identifying these patents. This part was proposed by the National Medical Products Administration. This part is under the jurisdiction of the National Technical Committee on Electrical Equipment in Medical Practice of Standardization Administration of China (SAC/TC10). This part was drafted by: Shanghai Testing & Inspection Institute for Medical Devices, BMC Medical Co., Ltd. The main drafters of this part. He Jun, Chen Bei, Chen Xingwen, Hou Bingying, Gu Zhengyu. Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard. Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

1 Scope

YY 9706.111 is the collateral standard for medical electrical equipment used at home. The home is not a hospital: the mains supply is less reliable and less well earthed, there is no biomedical engineering department, children and pets are present, the device may be

dropped or used in a bathroom, and the operator is a patient or a relative rather than a trained clinician. This standard adds the requirements that follow from that, covering mechanical robustness, ingress protection, electrical safety under domestic supply conditions, usability and the instructions a lay user actually needs. Home care is expanding rapidly in China with ventilators, oxygen concentrators and monitors moving out of hospitals. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.

1.1 * Scope This part specifies the requirements for the basic safety and essential performance of medical electrical equipment and medical electrical systems (hereinafter referred to as ME EQUIPMENT and ME SYSTEMS) for use in the home healthcare environment. This part applies to ME EQUIPMENT and ME SYSTEMS intended for use in the home healthcare environment, as specified by the manufacturer in the instructions for use. This part applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a lay operator or by trained healthcare personnel. The home healthcare environment includes.

-- the dwelling place in which a patient lives;

-- other places where patients are present both indoors and outdoors, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present.

This part does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the emergency medical services environment, covered by YY 9706.112 or solely for use in professional healthcare facilities covered by GB 9706.1 without the additions of YY 9706.112 or this part. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the home healthcare environment, are within the scope of this standard. EXAMPLE. ME EQUIPMENT or ME SYSTEMS intended for both the home healthcare environment and the professional healthcare facility environment. NOTE 1: ME EQUIPMENT and ME SYSTEMS used in home healthcare environments can frequently be used in locations with unreliable electrical sources and poor electrical grounding. NOTE. See also YY 9706.108-2021. Compliance is checked by inspection of the instructions for use. 7.4.7 * Additional requirements for cleaning, disinfection and sterilization In addition to the requirements of 7.9.2.12 and 16.2

c), indent 3 of the general standard, for ME EQUIPMENT, ME SYSTEMS, their parts or accessories that are intended for other than single use and that can become contaminated through contact with the patient or with body fluids or expired gases during intended use, the instructions for use shall.

-- indicate the frequency of cleaning, cleaning and disinfection or cleaning and sterilization, as appropriate, of the ME EQUIPMENT, ME SYSTEMS, parts or accessories used on the same patient including methods for rinsing, drying, handling and storage between uses

(see 8.1 and 8.2); and EXAMPLE 1: Periodic cleaning and disinfection of a breathing system to prevent infection of a patient during chronic care.

-- if intended for multiple patient use, indicate that it is necessary to clean and disinfect or clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts or accessories between uses on different patients, including methods for rinsing, drying, handling and storage until re-use (see 8.1 and 8.2); EXAMPLE 2: Cleaning and disinfection of a thermometer following use to prevent patient cross infection.

-- indicate that the ME EQUIPMENT, ME SYSTEMS or accessories require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2).

Compliance is checked by inspection of the instructions for use.

7.4.8 Additional requirements for maintenance In addition to the requirements of 7.9.2.13 of the general standard, the instructions for use shall include.

-- the expected service life of the ME EQUIPMENT;

-- the expected service life of parts or accessories shipped with the ME EQUIPMENT; and

-- where the shelf life is less than the expected service life, the shelf life of parts or accessories shipped with the ME EQUIPMENT. Compliance is checked by inspection of the instructions for use. .....