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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 9706.112-2021

Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

医用电气设备 第1-12部分：基本安全和基本性能的通用要求 并列标准：预期在紧急医疗服务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 the technical contents in this Part are mandatory. The serial standards of Medical Electrical Equipment are divided into the following parts.

--- Part 1: General and Collateral Requirements;

--- Part 2: Particular Requirements. This Part is Part 1-12. This Part was drafted as per the rules stipulated in GB/T 1.1-2009. This Part uses redrafting method to modify and adopt IEC 60601-1-12.2014 Medical Electrical Equipment - Part1-12: General Requirements for Basic Safety and Essential Performance - Collateral Standard. Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended for Use in the Emergency Medical Services Environment. The major differences between this Part and IEC 60601-1-12.2014 are as follows.

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--- Regarding the normative references, this Part has made adjustments with technical differences to adapt to the technical conditions of China. The adjustments are reflected in Clause 2 "Normative References". The specific adjustments are as follows. ? Use GB 9706.1-2020 that modifies and adopts the international standard to replace IEC 60601-1.2005+AMD1.2012; ? Use YY 9706.102 that modifies and adopts the international standard to replace IEC 60601-1-2.2014; ? Use YY 9706.108 that modifies and adopts the international standard to replace IEC 60601-1-8.2006+AMD1.2012; ? Use YY/T 9706.106 that modifies and adopts the international standard to replace IEC 60601-1-6.2010+AMD1.2013; ? Use YY 9706.111 that modifies and adopts the international standard to replace IEC 60601-1-11; ? Use GB 4824 that equivalently adopts the international standard to replace CISPR 11.2009; ? Add the quotation of HB 6167.6, HB 6167.18, HB 6167.23.

--- Given that aircraft manufactured at home and abroad are used in China, while retaining the requirements of foreign standards, the requirements of domestic standards have been added; and relevant content has been added in 4.1, 10.1.4b) and 11, which is expressed Medical Electrical Equipment - Part 1-12: General Requirements for Basic Safety and Essential Performance - Collateral Standard. Requirements for Medical Electrical Equipment and Medical Electrical Systems Intended for Use in the Emergency Medical Services Environment

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1 Scope

YY 9706.112 is the collateral standard for medical electrical equipment used in emergency medical services: in ambulances, at roadsides and in helicopters. It adds to the general safety standard the requirements that follow from that environment rather than from any one device type, covering mechanical shock and vibration, temperature and humidity extremes, ingress of water and dust, operation on vehicle power and on battery, electromagnetic conditions in a vehicle, and legibility and operability by a clinician wearing gloves in poor light. A monitor or a ventilator qualified for a ward is not thereby qualified for an ambulance. Being a YY standard without the /T suffix, compliance is compulsory in China. It took effect in May 2023, and any device claiming EMS use is assessed against it.

1.1 * Scope This Part specifies the requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS (hereafter referred to as ME EQUIPMENT and ME SYSTEMS), which are intended for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT. This Part applies to the ME EQUIPMENT AND ME SYSTEMS, as indicated in the instructions for use by their MANUFACTURER, for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT (hereinafter referred to as EMS ENVIRONEMENT). NOTE 1: For the purposes of this Standard, the intent of the MANUFACTURER is indicated in the instructions for use. The RESPONSIBLE ORGANIZATION and the OPERATOR need to be

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aware that any other use outside the MANUFACTURER'S INTENDED USE can result in a HAZARDOUS SITUATION for the PATIENT. The EMS ENVIRONMENT includes - responding to and providing life support at the scene of an emergency to a PATIENT reported as experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care. - providing monitoring, treatment or diagnosis during transport between professional healthcare facilities. This Part does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the HOME HEALTHCARE ENVIRONMENT covered by YY 9706.111 or solely for use in professional healthcare facilities covered by GB 9706.1 without the additions of YY 9706.111 or this collateral standard. ME EQUIPMENT and ME SYSTEMS are often not solely intended supporting methods to be employed. The technical description shall describe methods that can be employed for longer periods. NOTE 3: Electrical power supply failure includes failure of the SUPPLY MAINS or any near depletion of INTERNAL ELECTRICAL POWER SOURCES. If an INTERNAL ELECTRICAL POWER SOURCE is not provided, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION that indicates a power supply failure. EXAMPLE 2: The SUPPLY MAINS voltage falls below the minimum value required for normal operation. If an INTERNAL ELECTRICAL POWER SOURCE is provided, the ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an automatic switchover from the SUPPLY MAINS to the INTERNAL ELECTRICAL POWER SOURCE. NOTE 4: A visual indication of this charging mode is required in 15.4.4 of the general standard. If an INTERNAL ELECTRICAL POWER SOURCE is used, the ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates that the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for ME EQUIPMENT operation. This TECHNICAL ALARM CONDITION shall provide for a sufficient time or for a sufficient number of PROCEDURES for an OPERATOR to act. A TECHNICAL ALARM CONDITION of at least LOW PRIORITY shall remain active until the INTERNAL ELECTRICAL POWER SOURCE is returned to a level that is above the ALARM LIMIT or until it is depleted. It shall not be possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION. Compliance is checked by inspection, functional testing and inspection of the RISK MANAGEMENT FILE. 8.3 * Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT ME EQUIPMENT that is not FIXED or PERMANENTLY INSTALLED shall be capable of being powered in its INTENDED USE for at least 20 min from an INTERNAL ELECTRICAL POWER SOURCE. If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of

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ESSENTIAL PERFORMANCE, the ME EQUIPMENT shall be equipped with a means for the OPERATOR to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

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