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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.252-2021

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

医用电气设备 第2-52部分：医用病床的基本安全和基本性能专用要求

Issued on: September 6, 2021 **Implemented on: May 1, 2024**

Issued by: National Medical Products Administration

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Foreword

This document was issued on 6 September 2021 by the National Medical Products Administration and takes effect on 1 May 2024.

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

All the technical contents in this Standard are mandatory. YY 9706 Medical Electrical Equipment serial standards can be divided into the following two parts.

--- Part 1: General and Collateral Requirements;

--- Part 2: Particular Requirements. This Part is Part 2-52 of YY 9706. This Part was drafted as per the rules specified in GB/T 1.1-2009. This Part replaced YY 0571-2013 Medical Electrical Equipment - Part 2: Particular Requirements for The Safety of Electrically

Operated Hospital Beds. Compared with YY 0571-2013, the major technical changes of this Part are as follows besides the editorial modifications.

--- Corresponding to the general standard, the structure of this Part is adjusted from the original 10 chapters and 57 clauses into 17 clauses;

--- Modify the scope and purpose content (see 201.1 of this Edition; Clause 1 of the 2013 Edition);

--- According to the original text of the IEC, this Part has made amendments to the obvious errors in YY 0571-2013 when describing the relevant content (see 201.9.2.3.1, sub-clause 201.13.14 of this Edition; 22.2.102, 52.5.101 of 2013 Edition);

--- Corresponding to the general standards, add the requirements for risk management (see 201.4.2.2 of this Edition);

--- Add test evaluation content and specify specific implementation methods of test evaluation (see Tables 201.101 and 201.102 of this Edition);

--- Add the requirement of identification mark (see 201.7.2.2.107 of this Edition);

--- In order to facilitate the understanding of the standard numbers and names in Annexes AA, BB, and CC, retain the standard number and name of the original IEC;

--- Add Bibliography (see bibliography of this Edition);

--- Add an index of terms and definitions (see 201.3 of this Edition). This Part used the redrafting method to modify and adopt IEC 60601-2-52.2009 Medical Electrical Equipment - Part 2-52: Particular Requirements for the Basic Safety and Essential Performance of Medical Beds. The technical differences and causes between this Part and IEC 60601-2-52.2009 are as follows.

--- Regarding normative references, this Part has made adjustment with technical differences to adapt to the technical conditions of China. The adjustments are concentrated in Clause 2 "Normative References"; and the specific adjustments are: Use GB/T 2423.7-2018 that equivalently adopt international standard to replace IEC 60068-2-31.2008. This Part made the following editorial modifications.

--- Incorporate the content of the International Standard Amendment IEC 60601-2-52.2009/AMD1.2015. Please note some contents of this Document may involve patents. The issuing agency of this Document shall not assume the responsibilities to identify these patents. This Part was proposed by National Medical Products Administration. This Part shall be under the jurisdiction of Subcommittee for Standardization of Medical Electronic Instrument of National Technical Committee for Standardization of Medical Electrical Appliance (SAC/TC 10/SC 5). Drafting organizations of this Part. Paramount Bed Co., Ltd.; and Shanghai Testing & Inspection Institute for Medical Devices. Chief drafting staffs of this Part. Huang Zhenfeng, Xu Chao, Zhuang Jun, Chen Pengzhong, and Cao Yan. The

historical editions replaced by this Part are as follows.

--- YY 0571-2005;

--- YY 0571-2013. Medical Electrical Equipment - Part 2-52: Particular Requirements for the Basic Safety and Essential Performance of Medical Beds 201.1 Scope, Object and Related Standards Clause 1 of the general standard1) applies, except as follows. 201.1.2 Object The object of this Part is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL BEDS as defined in 201.3.212 intended for ADULTS as defined in 201.3.219. 201.1.3 Collateral standards This Part refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this Part. 201.1.4 Particular standards In the 9706 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements. 201.2 Normative References Informative references are listed in the bibliography on page 61. 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. Clause 2 of the general standard applies except as follows. 201.3 Terms and Definitions For the purposes of this document, the terms and definitions given in GB 9706.1 apply, except as follows. 201.4 General Requirements Clause 4 of the general standard applies, except as follows. 201.5 General Requirements for Testing of ME Clause 5 of the general standard applies, except as follows. 201.6 Classification of ME EQUIPMENT and ME Clause 6 of the general standard applies, except as follows. .....

1 Scope

YY 9706.252 is the mandatory Chinese standard for powered medical beds. A hospital bed looks like furniture and is regulated as medical electrical equipment because of how people are hurt by it: entrapment between the mattress and the side rails, which has killed frail and confused patients; crushing by a powered mechanism; falls when a brake or a rail fails. The standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the dimensional limits that close entrapment gaps, the strength and stability of the frame, the powered adjustment and its controls, and the brakes and rails. Being a YY standard without the /T suffix, compliance is compulsory in China. It takes effect in May 2024.