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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.277-2023

Medical electrical equipment - Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

医用电气设备 第2-77部分：采用机器人技术的辅助手术设备的基本安全和基本性能专用要求

Issued on: January 13, 2023 **Implemented on: January 15, 2026**

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Foreword

This document was issued on 13 January 2023 by the National Medical Products Administration and takes effect on 15 January 2026.

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

It is classified under ICS 11.040.01, Chinese classification A11.

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting. The "Medical Electrical Equipment" series of standards are divided into two parts.

--- Part 1: General and parallel requirements;

--- Part 2: Special requirements. This document is Part 2-77. This document is modified to adopt IEC 80601-2-77.2019 "Medical Electrical Equipment Part 2-77: Robotic Assisted Surgery Particular requirements for basic safety and essential performance of equipment". The technical differences between this document and IEC 80601-2-77.2019 and their reasons are as follows.

--- Replaced IEC 60601-1.2005 AMD1.2012 with the normative reference GB 9706.1-2020, between the two documents The degree of consistency is modified to adapt to the technical conditions of our country and increase operability;

--- Replaced IEC 60601-1-2014 with normatively referenced YY 9706.102-2021, the degree of consistency between the two documents To be modified to adapt to the technical conditions of our country;

--- Replaced IEC 60601-1-6010 AMD1.2013 with the normatively referenced YY/T 9706.106-2021, between the two documents The degree of consistency among them is modified to adapt to the technical conditions of our country;

--- Deleted IEC 62366-1.2015;

--- Deleted 206.4.2 and 206.5, the revision of IEC 60601-1-6 in the original IEC is limited to changing the version number of the referenced standard And add informative notes to the new version of the referenced standard, which will be consistent with YY/T 9706.106-2021 after deletion. The following editorial changes have been made to this document.

---Changed the editorial errors of the original text of IEC (see.201.3.216 Note 2 and.201.9.2.2.4.4);

---Appendix EE.3.2 and Appendix EE.3.3 have added informative notes. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the National Medical Electrical Appliance Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) Focus on. Medical Electrical Equipment Part 2-77. Robotic Assisted Surgical Devices Particular requirements for basic safety and essential performance 201.1 Scope Except as described below, Chapter 1 of the general standard applies. 201.1.1 Scope replace. This document specifies Robotic Assisted Surgical Equipment (RASE) and Robotic Assisted Surgical Systems (RASS) for basic security and basic performance. This document applies to Robotic Assisted Surgical Equipment (RASE) and Robotic Assisted Surgical Systems (RASS), hereinafter collectively referred to as ME EQUIPMENT and ME SYSTEM. This document also applies to the interaction conditions and interface conditions of me equipment and me systems. If a clause or clause expressly states that it applies only to me equipment or me systems, the title and text of the clause or clause shall state so. if not this In either case, the relevant clause or subclause applies to both me equipment and me systems. If RASE or RASS or its annexes belong to the scope of other specific standards, in addition to this document, the specific standards also apply. For example. GB 9706.202 for high-frequency surgical equipment, GB 9706.218 for endoscopic equipment, and GB 9706.218 for laser equipment IEC 60601-2-22, GB 9706.237 for ultrasound equipment, YY 9706.246 for operating tables, etc. 201.1.2 Purpose replace. The purpose of this document is to establish specific

guidelines for robotically assisted surgical equipment and robotically assisted surgical systems. Basic safety and basic performance requirements 201.1.3 * Collateral Standard Supplement. This document refers to Chapter 2 of the General Standard as well as applicable collateral standards listed in Clause.201.2 of this document. YY 9706.102-2021 and YY/T 9706.106-2021 shall apply after modification in Chapter 202 and Chapter 206 respectively. GB 9706.103-2021, IEC 60601-1-9.2007/AMD1.2013 and YY 9706.111-2021 are not applicable. 201.1.4 Particular standards replace. In the 9706 series of standards, specific standards may modify, replace or delete general standards and collateral standards according to the specific me equipment under consideration. The requirements contained in the standard, and other basic safety and basic performance requirements may be supplemented. Particular standard requirements take precedence over general standards. In this document, GB 9706.1-2020 is referred to as the general standard. Collateral standards are indicated by their respective document numbers. The numbers of chapters and clauses in this document correspond to general standards by adding the prefix "201" (for example,.201.1 in this document corresponds to general standard No. 1

1 Scope

YY 9706.277 is the mandatory Chinese standard for robotically assisted surgical equipment, the systems in which a surgeon operates through a robotic manipulator rather than directly. It sets the particular requirements for basic safety and essential performance of such equipment on top of the general medical electrical safety standard, covering the control of the manipulator, what happens when a fault or a power failure occurs mid-procedure, the limits on motion, and the information and feedback the surgeon receives. Surgical robotics is a priority sector in Chinese medical technology, with domestic systems now competing directly with imported ones. Being a YY standard without the /T suffix, compliance is compulsory: this is the safety text a Chinese registration for a surgical robot is assessed against. It takes effect in January 2026.