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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1994-2025

**Vascular interventional surgical control system employing
robotic technology**

采用机器人技术的血管介入手术控制系统

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Table of Contents

1.Scope	1
2 Normative References	1
3.Terms and Definitions	1
4 Requirements	2
4.1 Interventional device control performance	2
4.2 Force Testing	3
4.3 Support arm adjustment range	3
4.4 Software Functions	3
4.5 Safety Features	3
4.6 Fusion Display of Third-Party Images	4
4.7 Consumable Component Performance	4
5.1 Interventional device control performance	5
5.2 Force Testing	8
5.3 Support arm adjustment range	9
5.4 Software Functions	9
5.5 Safety Features	9
5.6 Fusion Display of Third-Party Images	10
10 Appendix A (Informative) Vascular Interventional Surgical Control System	12

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the unit responsible for the standardization of medical robots. This document was drafted by: China National Institutes for Food and Drug Control, Center for Medical Device Evaluation of the National Medical Products Administration, and Beijing Municipal Institute of Medical Devices. Medical Device Testing and Research Institute, Shanghai Medical Device Testing and Research Institute, Beijing Weimai Medical Technology Co., Ltd., and Zhimai (Shanghai) Robotics Co., Ltd. Limited Liability Company, Siemens Healthineers Ltd.,

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1 Scope

YY/T 1994 is the standard a robotic catheter system has to answer to in China. It specifies the technical requirements for vascular interventional surgery control equipment and systems that use robotic technology, and describes the test methods that go with them. The requirements are grouped by what the machine has to do: control performance over the interventional device, force measurement, the adjustment range of the support arm, software functions, safety features, fusion display of third-party images, and the performance of the consumable components that load the device. Each requirement has a matching test clause, and an informative annex illustrates the system layout. The document defines the operation terminal, the execution terminal and the consumable component as distinct parts, which is how a Chinese reviewer will expect a submission to be structured. For a manufacturer of robotic interventional platforms, it is the reference the registration test report is written against.

This document specifies the technical requirements for vascular interventional surgery control equipment/systems employing robotic technology (hereinafter referred to as. interventional equipment), describing... The corresponding experimental methods are described. This document applies to vascular interventional surgery control devices/systems that utilize robotic technology.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. document.

GB/T 16886.7 Biological evaluation of medical devices - Part

3 Terms and Definitions

The terms and definitions defined in YY/T 1686 and the following terms and definitions apply to this document.

3.1 Vascular interventional surgical control equipment/system employing robotic technology
ment/system employing robotic technology A medical electrical device/system includes a means driven by a programmable medical electrical system for controlling interventional instruments to perform partial or complete procedures. Interventional vascular surgery.

Note. Refer to Appendix A, section A.1 for the schematic diagram.

3.2 vascular intervention Under the guidance of medical imaging equipment, interventional devices are used to diagnose or treat lesions inside blood vessels via a vascular approach.

Note. For a schematic diagram of interventional devices, please refer to Appendix A, section A.2.

3.3 operation terminal A device used to collect or record operator instructions.

3.4 Execution terminal A device mounted on a support arm to enable the equipment to perform its surgical tasks.

3.5 Consumable components A component connected to the actuator for loading interventional devices.

7 Ethylene oxide sterilization residue

YY/T 1686 Medical Electrical Equipment Using Robotics Technology. Terminology, Definitions, and Classification Pharmacopoeia of the People's Republic of China (2025 Edition, Volume IV)