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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1840-2023

General specifications for medical magnetic resonance equipment

医用磁共振成像设备通用技术条件

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Table of Contents

Foreword

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. 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. This document is drafted by: Shanghai Institute of Medical Device Inspection, Medical Device Technology Evaluation Center of the State Drug Administration. The main drafters of this document. Hu Sheng, Yang Pengfei, Yang Yu, Liu Jiong. General technical requirements for medical magnetic resonance imaging equipment

1 Scope

YY/T 1840 is the general technical specification for medical MRI equipment in China. It sets out what an MRI system has to deliver and how it is demonstrated, covering the image quality parameters that define the scanner's performance, the magnetic field and gradient characteristics, the radiofrequency system, and the environmental and operating conditions the equipment has to work within. It is the document that turns a manufacturer's specification sheet into something a purchaser or a regulator can verify, since MRI performance claims are otherwise stated in terms that differ from vendor to vendor. MRI is a high-value capital purchase for Chinese hospitals and one where the acceptance test matters commercially. The 2023 edition takes effect in January 2026. For a manufacturer this is the text a Chinese registration and an acceptance test both refer to.

This document specifies the requirements and test methods for medical magnetic resonance imaging equipment. This document is applicable to superconducting magnetic resonance imaging equipment, permanent magnetic magnetic resonance imaging

equipment and conventional magnetic resonance imaging equipment.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 7247.1 Safety of Laser Products Part

3 Terms and Definitions

The following terms and definitions defined in YY/T 0482-2022 apply to this document.

3.1 Composed of some sub-coil units, it is used to detect signals in a certain limited area, and is given by the combination of signal receiving links of each sub-coil. The resulting digital signal covers the entire coil area of the medium.

3.2 The main magnet used to generate the static magnetic field is a superconducting magnet in MRI equipment.

3.3 The main magnet used to generate the static magnetic field is an MRI device made of permanent magnetic material.

3.4 The main magnet used to generate the static magnetic field is a magnetic resonance imaging device with a constant conduction magnet.