ICS 11.040.01
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1928-2023

Terminology and classification of medical electrical equipment intended for use in the magnetic resonance environment

预期用于磁共振环境的医用电气设备的术语和分类

Issued on: November 22, 2023 **Implemented on: December 1, 2024**

Issued by: National Medical Products Administration

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 of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is provided by the National Technical Committee for Standardization of Medical Electrical Appliances, Medical Electronic Instruments Standardization Subcommittee (SAC/TC10/SC5) Centralized. This document was drafted by: National Medical Products Administration Medical Device Technical Evaluation Center, Shanghai Medical Device Inspection Institute, Fudan University University, Beijing Medical Device Evaluation and Inspection Center, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., and Lanzhou University. The main drafters of this document are. Wang Jing, Hong Wei, Yang Pengfei, Wu Xiaomei, Chen Ran, Li Yonghua, Tao Hua, and Yao Aiping. Medical electrical equipment intended for use in a magnetic resonance environment Terminology and classification

1 Scope

YY/T 1928 is the document that fixes what MR Safe, MR Conditional and MR Unsafe mean in China. It specifies the terminology used for medical electrical equipment intended to be used in the magnetic resonance environment and sets out how such equipment is classified. That vocabulary is the foundation everything else rests on: a labelling claim, an instruction for use, a hospital protocol deciding whether an implanted or attached device may enter the scanner room all depend on these definitions being applied consistently. For a manufacturer of infusion pumps, monitors, implants or accessories, this is the standard that determines which MR classification may be claimed and how it must be expressed on the device and in its documentation. It is the reference a Chinese reviewer applies to any MR compatibility claim.

This document defines the terminology for medical electrical equipment intended for use in

a magnetic resonance environment and specifies the Classification of gas equipment. This document applies to medical electrical equipment used in a magnetic resonance environment.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Magnetic resonance; MR The phenomenon of resonance absorption of electromagnetic field energy of a specific frequency by a group of atomic nuclei placed in a magnetic field. NOTE. In this document, the magnetic field generally refers to the composite field of the static magnetic field and the gradient field of the magnetic resonance equipment used for medical diagnosis. [Source: YY 9706.233-2021,.201.3.217, modified]

3.2 MRequipment Medical electrical equipment intended for magnetic resonance imaging of humans (3.5), including all hardware and software from the mains power supply to the display monitor part. [Source: YY 9706.233-2021,.201.3.218, modified]

3.3 MR system The combination of magnetic resonance equipment (3.2), accessories (including display, control and energy supply devices) and controlled access area (if any). [Source: YY 9706.233-2021,.201.3.220]

3.4 MRenvironment The three-dimensional volume of space around the magnetic resonance device (3.2), which includes the volume of space inside the Faraday shield and the volume of space inside the

0.5 mT The spatial volume within the contour of the magnetic field contour (

5 Gauss line). This three-dimensional spatial volume refers to the exposure of the medical device to the magnetic resonance equipment and its accessories Areas where electromagnetic fields may cause danger. [Source: ASTM F2503-20, 3.1.10, modified]