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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.1-2020

Replacing GB 9706.1-2007, GB 9706.15-2008

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

医用电气设备 第1部分：基本安全和基本性能的通用要求

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Standardization Administration of the PRC..

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Foreword

GB 9706 "Medical electrical equipment" is divided into the following parts:

- Part 1: General requirements for basic safety and essential performance;

the range 1 MeV to 50 MeV;

- Part 2-4: Particular requirements for the safety of cardiac defibrillators;

of therapeutic X-ray equipment operating in the range 10 kV to 1 MV;

performance of gamma beam therapy equipment;

performance of automatically-controlled brachytherapy after-loading equipment;

performance of surgical, cosmetic, therapeutic and diagnostic laser equipment;

performance of X-ray tube assemblies for medical diagnosis;

performance of equipment for extracorporeally induced lithotripsy;

performance of ultrasonic medical diagnostic and monitoring equipment;

performance of X-ray equipment for computed tomography;

performance of X-ray equipment for radiography and radioscopy;

performance of dental extra-oral X-ray equipment;

performance of dental intra-oral X-ray equipment;

performance of hearing instruments and hearing instrument systems.

This Part is drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB 9706.1-2007 "Medical electrical equipment - Part 1: General requirements for safety" and GB 9706.15-2008 "Medical electrical equipment - Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems". This Part is based on GB 9706.1-2007 and integrates all the contents of GB 9706.15-2008. Compared with GB 9706.1-2007, in addition to editorial changes, the main technical changes are as follows:

- Incorporate the contents of GB 9706.15 and YY/T 0708 into this Part;

- ADD requirements for essential performance (see Clause 4);

- ADD the concept of expected service life (see 4.4);

- ADD content related to risk management (see 4.2);

- ADD different requirements for operator protection and patient protection (see Clause 8);

- Modify the test requirements for protection against electric shock (see

Clause 8; Clause 3 of the 2007 edition);

- ADD relevant requirements for mechanical safety (see Clause 9);

- ADD fire prevention requirements (see 11.3).

This Part uses the redraft law to modify and adopt IEC 60601-1:2012 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

The technical differences between this Part and IEC 60601-1:2012 and their reasons are as follows:

- As for the normative references, this Part has made adjustments with technical differences, to adapt to the technical conditions of China. The adjustments are reflected in Clause 2 “Normative references”. The specific adjustments are as follows:

2011 which modifies and adopts the international standard;

- ADD the requirements for the mains plug to 8.11.3.1.

- Modify the footnote of Table 20 to read "a The values in this table are taken This Part also made the following editorial changes:

CSV/COR1:2012; USE a vertical double line (‖) to mark the blank position on the outer side of the corresponding clause;

- Include the technical errata content of IEC 60601- 1:2005/AMD1:2012/COR1:2014; USE a vertical double line (‖) to mark the blank position on the outer side of the corresponding clause;

- ADD A.5 to Annex A, which lists the abbreviations and acronyms used in the standard;

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority of this document shall not be held responsible for identifying any or all such patent rights.

This Part was proposed by and shall be under the jurisdiction of National Medical Products Administration.

Drafting organizations of this Part: Shanghai Testing and Inspection Institute for Medical Devices, Beijing Institute of Medical Device Testing, Liaoning Medical Device Test Institute, Zhejiang Institute of Medical Device Testing, Shenzhen Mindray Bio-medical Electronics Co., Ltd., General Electric Medical System Trade Development (Shanghai) Co., Ltd., Siemens Shanghai Medical Equipment Ltd., Philips Healthcare (Suzhou) Co., Ltd.

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The previous editions of the standard replaced by this Part were released as follows:

1 Scope, object and related standards