CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.220-2021

Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

医用电气设备 第2-20部分：婴儿转运培养箱的基本安全和基本性能专用要求

Issued on: March 9, 2021 **Implemented on: May 1, 2023**

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Foreword

This document was issued on 9 March 2021 by the National Medical Products Administration and takes effect on 1 May 2023.

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

It is classified under Chinese classification C39.

All technical content of this part is mandatory. "Medical Electrical Equipment" safety requirements series standards are mainly composed of two parts.

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

---Part 2: Specific requirements for basic safety and basic performance. This part is part 2-20 of "Medical Electrical Equipment". This section was drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0827-2011 "Medical Electrical

Equipment Part 2: Special Requirements for the Safety of Transport Incubators". This part and Compared with YY 0827-2011, the main technical changes except for editorial changes are as follows.

---Revision of the original standard in accordance with the content of IEC 60601-2-20.2009 A1 (2016), the structure and layout of this standard have changed The original 11 chapters have been changed to 17 chapters, and electromagnetic compatibility requirements and tests have been added;

---Infant terms and definitions have been added (see.201.3.207);

---The concept and requirements of basic performance have been added (see.201.4.3.11);

---Modified the test environment temperature (see.201.5.3,.2011 edition of 10);

---Added relevant requirements for weight scales (see.201.12.1.116);

---Added the requirements of the programmable medical electrical system (PEMS) (see.201.14);

---The electromagnetic compatibility requirements and tests of ME equipment and ME systems have been added (see 202);

---Modified the requirements and testing of electromagnetic compatibility (see 202, 36 in the 2011 edition);

---Added the index of references and citation definitions and terms (see index). This part is revised and adopted IEC 60601-2-20.2009 "Medical Electrical Equipment Part 2: Basic Safety and Safety of Infant Transport Incubators" Special Requirements for Basic Performance" and Amendment 1 (2016). The technical differences between this part and IEC 60601-2-20.2009 AMD1 (2016) and the reasons are as follows.

---Regarding normative reference documents, this section has made adjustments with technical differences to adapt to my country's technical conditions and adjustments It is concentratedly reflected in.201.2 "Normative Reference Documents", and the specific adjustments are as follows. * Replace IEC 60601-1-2.2007 with YY 9706.102-2021 which is equivalent to adopting international standards; * Deleted ISO 32 and ISO 407; * Added GB/T 7144 and GB/T 15382;

---When the standard involves a series of standards and different versions of the same standard, due to the series of standards that have not been converted in the country Or the relevant version of the standard has not been converted. Therefore, in order to maintain the meaning consistent with the original text, the international standard number is retained;

--- Change 3.139 in.201.1.4 to 3.147. Please note that some of the contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents. This part was proposed by the State Drug Administration. This part is organized by the National Medical Electrical Appliance Standardization Technical

Committee Medical Electronic Instrument Standardization Subcommittee (SAC/TC10/SC5) Focus. Drafting organizations of this section. Ningbo Dawei Medical Devices Co., Ltd., Shanghai Medical Device Testing Institute, Shanghai Draeger Medical Devices Limited company. The main drafters of this section. Lin Dingyu, Hong Wei, Chen Huiming, Zhuoyue, Guo Yongbing, Yan Cuiren. The previous version of the standard replaced by this part.

---YY 0827-2011.

Introduction

This section deals with the basic safety and basic performance specific requirements of the infant transport incubator. This part amends and supplements GB 9706.1- 2007 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Basic Performance", hereinafter referred to as "General Standards." Essentials of this section Seek priority over general standards. The names of the chapters or articles in this part are consistent with the names of the corresponding chapters or articles in the general standard. Chapters or articles not mentioned in this section, these chapters or articles in general standards or specific parallel standards apply without modification. Any part of the general standard that is relevant but not applicable has been pointed out in this section. The numbering of the chapters and articles in this part corresponds to the general standard by adding the prefix "201" (for example,.201.1 of this part corresponds to the general standard The content of Chapter 1), or by adding the prefix "20x" to correspond to the applicable parallel standard, where x is the international standard corresponding to the parallel standard. The last digit of the number (for example, 202.4 of this part corresponds to the 4th in the international standard IEC 60601-1-2 corresponding to the parallel standard YY 9706.102 The content of the chapter, 203.4 in this part corresponds to the content of Chapter 4 in the international standard IEC 60601-1-3 corresponding to the parallel standard GB 9706.103, and many more). The bars, figures and tables added to the general standard are numbered starting from.201.101. Since the number defined in the general standard ranges from 3.1 to 3.147, the definitions added in this section are numbered starting from.201.3.201. This section adds appendix numbers as AA, BB, etc., and increases the number of items as aa), bb), etc. Appendix AA correspondingly gives some important requirements (there are clauses with "*" after the clause number). considering Understanding the principles of these requirements is not only conducive to the correct implementation of the standards, but also appropriately promotes the transformation of clinical practice and the development of technology, thereby producing Requirements for revision of health standards. But this part of the appendix does not belong to the requirements of this part. Medical electrical equipment Part 2-20: Baby transfer Special requirements for the basic safety and basic performance of the incubator 201.1 Scope, purpose and related standards In addition to the following, Chapter 1 of the general standard applies. 201.1.1 Scope Substitute. This section applies to the basic safety and basic performance requirements of the infant transfer incubator, such as the infant transfer

incubator, also known as ME equipment. If a chapter or article clearly states that it is only applicable to ME equipment or ME systems, the title and the text of the chapter or article will explain. if not In this case, the relevant chapters or articles apply to both ME equipment and ME systems. In addition to the general standards 7.2.13 and 8.4.1, the hazards caused by the expected physiological effects of the ME equipment or ME system within the scope of this part There are no specific requirements for risk (source) in this section. Note. See 4.2 of the General Standard. This part specifies the safety requirements for infant transfer incubators, but if the manufacturer states in its risk management document Compared with the treatment benefit of the device, the risk is at an acceptable level, so a special clause is used to demonstrate the equivalent safety. Compatible alternatives can be considered compliance. This section does not apply.

---Medical heating equipment that supplies heat through blankets, cushions and mattresses, please refer to YY 0834 for details;

---Infant incubators that are not infant transfer incubators, please refer to GB 11243 for details;

---Infant radiant warmer; please refer to YY 0455 for details;

---Infant light therapy equipment; please refer to YY 0669 for details. 201.1.2 Purpose Substitute. The purpose of this section is to specify the basic safety and basic performance requirements for the infant transport incubator defined in.201.3.208: It Minimize the risk to patients and operators, and specify tests to identify whether they meet the requirements. 201.1.3 Parallel standards increase. This section refers to those listed in Chapter 2 of the General Standards and applicable parallel standards in this section.201.2. YY 9706.102 applies to the revised 202: GB 9706.103 and YY/T 9706.10 are not applicable. All others have been published on The parallel standards of the GB 9706.1 series are applicable. 201.1.4 *Specific standards Substitute. In the GB 9706 series of standards, for the specific ME equipment considered, the specific standards may modify, replace or delete the applicable standards in this standard. Use requirements, and may increase other basic safety and basic performance requirements. The requirements of specific standards take precedence over the requirements of general standards.

1 Scope

YY 9706.220 is the mandatory Chinese standard for infant transport incubators, the units that carry a sick newborn between hospitals or between departments. Everything that makes a ward incubator safe has to keep working while the unit is wheeled, loaded into an ambulance, driven and unloaded: the temperature control has to hold with the doors opening and ambient conditions changing, the battery has to outlast the journey, the gas supply has to be self-contained, and the enclosure has to protect the infant against the shock and vibration of transport. The standard sets those particular requirements on top of the general medical electrical safety standard. Neonatal transport networks have expanded