CCS C39

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.221-2021

Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers

医用电气设备 第2-21部分：婴儿辐射保暖台的基本安全和基本性能专用要求

Issued on: September 6, 2021 **Implemented on: May 1, 2024**

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Foreword

This document was issued on 6 September 2021 by the National Medical Products Administration and takes effect on 1 May 2024.

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. The "Medical Electrical Equipment" series of standards is divided into two parts.

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

--- Part 2: Particular requirements for basic safety and basic performance. This part is part 2-21 of medical electrical equipment. This section is drafted in accordance with the rules given in GB/T 1.1-2009. This part replaces YY 0455-2011 "Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Radiant Warmers". Compared with YY 0455-2011, the main changes in this part are as follows.

--- Revise the original standard according to the content of IEC 60601-2-21.2009 A1 (2016), the structure and arrangement of this standard have changed. Changed from the original 11 articles to 17 chapters, and additionally increased the requirements and tests of electromagnetic compatibility.

--- Added infant terms and definitions (see.201.3.203);

--- Introduced the concept and requirements of basic performance (see.201.4.3.101);

--- Modified the test ambient temperature (see.201.5.3, 10.2.1 of the 2011 edition);

--- Added the external marking requirements for "Oxygen Monitoring" (see.201.7.2.101);

--- Added relevant requirements for weight scales (201.12.1.105);

--- Added requirements for Programmable Medical Electrical Systems (PEMS) (see.201.14);

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

--- Added references, citation definitions and an index of terms (see Index). This part of the revision adopts the international standard IEC 60601-2-21.2009 "Medical Electrical Equipment Part 2: Safety of Infant Radiant Warmers" Specific Requirements" and Amendment No. 1 in 2016 IEC 60601-2-21.2009/AMD1.2016. This part of IEC 60601-2-21.2009 AMD1.2016 has made the following modifications.

--- Regarding normative reference documents, this part has made adjustments with technical differences to adapt to the technical conditions of our country and the adjustment situation Centrally reflected in.201.2 "normative reference documents", the specific adjustment is. use the revised YY 9706.102 generation of international standards Replace IEC 60601-1-2;

--- changed 3.139 in.201.1.4 to 3.147;

--- Changed the note in Figure.201.102, deleted "(1)=Mattress", and added "All dimensions are in millimeters";

--- Table.201.101, in the second row of the second column, the IEC original text is "and", a clerical error, this part is translated as "or". Please note that some content of this document may be patented. The issuing authority of this document assumes no responsibility for identifying these patents. This part is proposed by the State Drug Administration. This part is regulated by the National Medical Electrical Standardization Technical Committee Medical Electronic Instrument Standardization Sub-Technical Committee (SAC/TC10/SC5) focal point. This section is drafted by: Ningbo Dawei Medical Equipment Co., Ltd., Shanghai Medical Equipment Testing Institute, Shanghai Dräger Medical Equipment Ltd. The main drafters of this section. Lin Dingyu, Hong Wei, Cai Jiaxi, Zhuozhuo, Guo Yongbing, Yan Cuiren. The previous versions of the standards replaced by this part are as follows: YY 0455-2011.

Introduction

This part deals with the basic safety and basic performance requirements for infant radiant warmers. This part corrects and supplements GB 9706.1-2020 "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance", hereinafter referred to as "General Standard". The requirements of this part are preferred Precedes Common Criteria. The names of the chapters or subclauses in this part are the same as those of the corresponding chapters or subclauses in the general standard. For chapters or subclauses not mentioned in this section, these chapters or subclauses in the General Standard or specific collateral 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 clauses of this part corresponds to the general

standard by prefixing "201" (for example,.201.1 of this part corresponds to the general standard 1 chapter), or by adding the prefix "20x" to correspond to the applicable collateral standard, where "x" is the corresponding international standard number of the collateral standard The last digit (for example, 202.4 of this part corresponds to Chapter 4 of the international standard IEC 60601-1-2 corresponding to the collateral standard YY 9706.102 203.4 in this part corresponds to the parallel standard GB 9706.103 corresponds to the content of Chapter 4 in the international standard IEC 60601-1-3, etc. Wait). Bars, figures and tables added to the Common Criteria are numbered starting from.201.101. Since the numbers defined in the general standard are 3.1~3.147, the definitions added in this section are numbered from.201.3.201. The numbers of the appendices added to this part are AA, BB, etc., and the numbers of the added items are aa), bb), etc. The rationale for some important requirements (clauses with "*" after the clause number) are given in Appendix AA. taking into account the rationale The rationale for understanding these requirements not only facilitates the correct implementation of the standard, but also appropriately promotes changes in clinical practice and technological development, resulting in Standard revision requirements, but this part of the appendix does not belong to the requirements of this part. Medical Electrical Equipment Part 2-21: Infant Radiation Particular requirements for basic safety and basic performance of warmers 201.1 Scope, Purpose and Related Standards Except for the following, Chapter 1 of the General Standard applies. 201.1.1 Scope Substitute. This part applies to the requirements for the basic safety and essential performance of infant radiant warmers, as specified in this part of infant radiant warmers Defined equipment, also known as ME equipment. If a chapter or article is clearly stated to apply only to ME EQUIPMENT or ME SYSTEMS, the title and the body of the chapter or article will state that. if not In this case, the relevant chapter or clause applies to both ME EQUIPMENT and ME SYSTEM. Hazards resulting from expected physiological effects of ME EQUIPMENT and ME SYSTEMS within the scope of this standard, in addition to 7.2.13 and 8.4.1 of the general standard (source), not specifically required in this section. Note. See 4.2 of the general standard. The safety requirements for infant radiant warmers specified in this section, but if the manufacturer describes in its risk management documentation the risk of If the risk is at an acceptable level compared to the therapeutic benefit of the device, then a special Compliant alternatives may be considered compliant. This section does not apply to.

--- Medical heating equipment for heating through blankets, pads and mattresses, see YY 0834 for details;

---Infant incubator; see GB 11243 for details;

---Infant transfer incubator; see YY 0827 for details;

--- Infant light therapy equipment; see YY 0669 for details. 201.1.2 Purpose Substitute. The purpose of this section is to specify the essential safety and essential performance requirements specific to infant radiant warmers as defined in.201.3.204, which Minimize

risks to the patient and operator, and specify tests to identify compliance with requirements. 201.1.3 Tied standards Increase. This part refers to those listed in Chapter 2 of the General Standard and the applicable collateral standards in Chapter.201.2 of this part. YY 0505 applies to clause 202 as amended. GB 9706.12 and IEC 60601-1-10 do not apply. All others have been published in The parallel standards of GB 9706.1 series apply. 201.1.4 *Particular standard Substitute. In the 9706 series of standards, specific standards may modify, replace or delete applicable requirements in this section for the specific ME EQUIPMENT under consideration. requirements, and may add other essential safety and essential performance requirements.

1 Scope

YY 9706.221 is the mandatory Chinese standard for infant radiant warmers, the open resuscitaires under which a newborn is dried, examined and stabilised while an overhead element keeps it warm. The design trades the thermal efficiency of a closed incubator for immediate access, which puts the whole safety case on the control of radiant heat: a newborn on an open platform loses heat rapidly and burns easily, and cannot signal either. The standard sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the irradiance and its distribution, the skin temperature control and its alarms, and the mechanical stability of the platform. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in May 2024.