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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.219-2021

Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators

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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 of Standardization Documents"

Drafting.

This document is part 2-19 of GB 9706 "Medical Electrical Equipment". GB 9706 has released the following parts.

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

---Part 1-3.General requirements for basic safety and basic performance Parallel standard.

Radiation protection of diagnostic X-ray equipment;

---Part 2-1.Specific requirements for the basic safety and basic performance of electron accelerators with an energy of 1MeV to 50MeV;

---Part 2-2.Special requirements for the basic safety and basic performance of high-frequency surgical equipment and high-frequency accessories;

---Part 2-3.Special requirements for basic safety and basic performance of shortwave treatment equipment;

---Part 2-5.Special requirements for the basic safety and basic performance of ultrasonic physical therapy equipment;

---Part 2-6.Special requirements for the basic safety and basic performance of microwave therapy equipment;

---Part 2-8.Special requirements for the basic safety and basic performance of therapeutic X-ray equipment with an energy of 10kV to 1MV;

---Part 2-11.Special requirements for the basic safety and basic performance of gamma beam therapy equipment;

---Part 2-12.Special requirements for the basic safety and basic performance of intensive care ventilators;

---Part 2-13.Special requirements for the basic safety and basic performance of the anesthesia workstation;

---Part 2-16.Specific requirements for the basic safety and basic performance of hemodialysis, hemodiafiltration and hemofiltration equipment;

---Part 2-17.Special requirements for the basic safety and basic performance of automatic control brachytherapy after-installation equipment;

---Part 2-18.Specific requirements for the basic safety and basic performance of endoscopic equipment;

---Part 2-19.Special requirements for basic safety and basic performance of infant incubators;

---Part 2-24.Special requirements for basic safety and basic performance of infusion pumps and infusion controllers;

---Part 2-25.Special requirements for basic safety and basic performance of electrocardiograph;

---Part 2-26.Special requirements for the basic safety and basic performance of EEG machines;

---Part 2-27.Special requirements for basic safety and basic performance of ECG monitoring equipment;

---Part 2-28.Special requirements for the basic safety and basic performance of medical diagnostic X-ray tube components;

---Part 2-29.Specific requirements for the basic safety and basic performance of radiotherapy simulators;

---Part 2-36.Special requirements for the basic safety and basic performance of in vitro lithotripsy equipment;

---Part 2-37.Special requirements for the basic safety and basic performance of ultrasonic diagnostic and monitoring equipment;

---Part 2-39.Special requirements for the basic safety and basic performance of peritoneal dialysis equipment;

---Part 2-43.Special requirements for the basic safety and basic performance of interventional X-ray equipment;

---Part 2-44.Special requirements for the basic safety and basic performance of X-ray computed tomography equipment;

---Part 2-45.The basic safety and basic performance of mammography equipment and mammography stereotaxic devices

Require;

---Part 2-54.Special requirements for the basic safety and basic performance of X-ray photography and fluoroscopy equipment;

---Part 2-60.Special requirements for basic safety and basic performance of dental equipment;

---Part 2-63.Special requirements for the basic safety and basic performance of extraoral imaging dental X-ray machines;

---Part 2-65.Specific requirements for the basic safety and basic performance of dental X-ray machines for intraoral imaging.

This document replaces GB 11243-2008 "Medical Electrical Equipment Part 2.Special Requirements for the Safety of Infant Incubators", and is in line with GB 11243-2008

Compared with.2008, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---The concept and requirements of basic performance have been added (see.201.4.

---Changed the definition of "air temperature controlled incubator" (see.201.3.201, 2.1.103

in.2008 edition);

---Changed the illustration of the temperature sensor (see Figure.201.101, Figure 102 in the.2008 edition);

---Added "infant" terms and definitions (see.201.3.208);

--- Changed the terminology and revised "incubator" to "infant incubator" (see.201.3.209, 2.1.101 of the.2008 edition);

---Added relevant requirements for weight scales (see.201.12.1.112);

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

--- Increase the electromagnetic compatibility requirements and testing of ME equipment and ME systems (see Chapter 202).

This document is revised and adopted IEC 60601-2-19.2016 "Medical Electrical Equipment Part 2-19.Basic Safety and Basics of Infant Incubators"

Specific requirements for this performance".

The technical differences between this document and IEC 60601-2-19.2016 and the reasons are as follows.

---Regarding normative reference documents, this document has made adjustments with technical differences to adapt to my country's technical conditions and adjustments.

The situation is collectively reflected in.201.2 "Normative Reference Documents", and the specific adjustments are as follows.

* Replace IEC 60601-1-2 with YY9706.102-2021 which is modified to adopt international standards.

--- Change.201.3208 in.201.1.2 to.201.309.

---Because there are 147 terms and definitions in GB 9706.1-2020, the 3.139 in.201.1.4 is changed to 3.147.

--- Change.201.12.1.108 in.201.7.9.2.8 to.201.12.1.107.

The following editorial changes have been made to this document.

---Replace the international documents in the references with standards-adoption relations with Chinese documents, as follows.

* Replace IEC 61672-1 with GB/T 3785.1 which is equivalent to adopting international standards;

* Replace IEC 60601-2-20 with YY9706.220 modified to adopt international standards;