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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 9706.260-2020

Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

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Foreword

GB 9706 "Medical Electrical Equipment" is divided into 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 basic safety and basic performance of electron accelerators with energy from 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 short-wave treatment equipment;

---Part 2-4.Special requirements for the basic safety and basic performance of cardiac defibrillators;

---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 basic safety and basic performance of anesthesia workstations;

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

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

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

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

---Part 2-22.Special requirements for basic safety and basic performance of laser equipment for surgery, plastic surgery, treatment and diagnosis;

---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.Specific 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.Specific 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.Special requirements for the basic safety and basic performance of mammography equipment and mammography stereotaxic devices;

---Part 2-54.Specific 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 intraoral imaging dental X-ray machines;

---Part 2-66.Special requirements for basic safety and basic performance of hearing equipment and hearing equipment system.

This part is part 2-60 of GB 9706.

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

This part uses the redrafting law to modify and adopt IEC 80601-2-60.2012 "Medical Electrical Equipment Part 2-60.Dental Equipment

Special requirements for basic safety and basic performance.

The technical differences between this part and IEC 80601-2-60.2012 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.

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

* Replace IEC 60825-1 with GB 7247.1 which is equivalent to adopting international standards;

* Replace ISO 1942 (all parts) with GB/T 9937 (all parts). The degree of consistency between the parts of the two standards is as follows.

* GB/T 9937.1-2008 oral vocabulary part 1.basic and clinical terms (ISO 1942-1.1989, IDT);

* GB/T 9937.2-2008 Dental Vocabulary Part 2.Dental Materials (ISO 1942-2.1989, IDT);

* GB/T 9937.3-2008 Dental Vocabulary Part 3.Dental Devices (ISO 1942-3.1989, IDT);

* GB/T 9937.4-2005 Dental Terminology Part 4.Dental Equipment (ISO 1942-4.1989, IDT);

* GB/T 9937.5-2008 Oral Vocabulary Part 5.Terms related to testing (ISO 1942-5.1989, IDT).

---The IEC 61180-1 and IEC 61180-2 cited in the original text have been replaced by IEC 61180.2016, so they are in.201.2 and.201.8.

In 9.1.12, IEC 61180.2016 is used to replace IEC 61180-1 and IEC 61180-2.

---ISO 7785-2 and ISO 11498 cited in the original text have been replaced by ISO 14457.2017, so they are in.201.2,.201.11.1.3.

Use ISO 14457.2017 instead of ISO 7785-2 and ISO 11498.

---Modify the translations of.201.1.3 and.201.1.4 to be consistent with domestic standards.

This section also made the following editorial changes.

--- The appendix under "Summary and Basic Principles of Insulation" in Appendix AA is deleted, which is consistent with GB/T 16935.1-2008

The table F.1 is consistent and will not be repeated;

--- Deleted the "term index".

Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents.

This part is proposed and managed by the State Drug Administration.

Medical Electrical Equipment Part 2-60.