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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 9706.241-2020

Replacing YY 0627-2008

**Medical electrical equipment - Part 2-41: Particular
requirements for the basic safety and essential performance of
surgical luminaires and luminaires for diagnosis**

医用电气设备 第2-41部分：手术无影灯和诊断用照明灯的基本安全和基本性能专用要求

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Table of Contents

Bibliography	28
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Foreword

This document was issued on 27 September 2020 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 ICS 11.040.01, Chinese classification C40.

It replaces YY 0627-2008, which is superseded.

All technical content in this section is mandatory: The "Medical Electrical Equipment" series of standards is divided into two parts:

---Part 1: General and parallel requirements;

---Part 2: Special requirements: This part is part 2-41: This section was drafted in accordance with the rules given in GB/T 1:1-2009: This part replaces YY 0627-2008 "Medical electrical equipment Part 2: Special requirements for the safety of surgical shadowless lamps and diagnostic lamps Compared with YY 0627-2008, the main technical changes except for editorial changes are as follows:

---Added normative reference documents (see:201:2);

---Modified the term and definition of "beam depth" (see:201:3:203, 2:109 of YY 0627-2008);

---Modified the term "failure protection" (see:201:3:204, 2:10:101 of YY 0627-2008);

---Modified the term "detachable handle" (see:201:3:210, 2:1:101 of YY 0627-2008);

--- Added terms and definitions "single surgical shadowless lamp" (see:201:3:213);

--- Deleted the term "safety extra low voltage" (see 2:4:3 of YY 0627-2008);

--- The term "applied part" was deleted, and it was added in the form of a note in the protection against electric shock (see 2:1:5 of YY 0627-2008, 201:6:2);

--- Added "Requirements for Special Color Rendering Index R9" (see:201:7:9:2:1);

--- Deleted the material heat resistance and flame retardant test (see 55:1 of YY 0627-2008);

---Deleted the material composition requirements [see 59:1d) of YY 0627-2008]: This part

uses the redrafting method to modify and adopt IEC 60601-2-41:2013 "Medical Electrical Equipment Part 2-41: Surgical Shadowless Lamps And special requirements for basic safety and basic performance of diagnostic lamps: Compared with IEC 60601-2-41:2013, there are technical differences in this part: The clauses related to these differences have been passed on the outer margins: The vertical single line (|) in the blank position is marked, and Appendix BB gives a list of the corresponding technical differences and their reasons: This section has made the following editorial changes:

---Term order adjustment: Adjust the serial number:201:3:204 of the term "spot center" in IEC 60601-2-41:2013 to:201:3:201, which His serial number has been postponed: Because the "spot center" is the basic point of a series of definitions, it is strictly and orderly after adjustment, and the order is more reasonable:

---IEC 60601-2-41:2013:201:5:4 The warm-up time of other light sources does not exceed 1% according to the performance change per 100h Determine the warm-up time, where 100h is an editorial error, and it is 10h in IEC 60601-2-41:2000, which is changed to 10h:

--- A note has been added in:201:9:5:1:101 of this part:

---A note has been added in this section:201:12:1:102:1:2:

--- The chapter number of:201:3:103 failure protection in Appendix AA is wrong, and it is changed to:201:3:204 in this section:

--- Deleted the term index after the IEC 60601-2-41:2013 reference: 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 was proposed by the State Drug Administration: This part is organized by the National Optical and Photonics Standardization Technical Committee Medical Optics and Instrument Sub-Technical Committee (SAC/TC103/ SC1) Centralized: Drafting unit of this section: Zhejiang Medical Device Inspection and Research Institute: The main drafters of this section: Wang Jingtao, Jia Xiaohang, He Tao, Hu Yiping, Peng Jianhua: The previous versions of the standards replaced by this part are as follows:

---YY 0627-2008: Medical electrical equipment-Part 2-41: Surgical shadowless lamps And basic safety and basic performance of diagnostic lamps Dedicated requirements 201:1 Scope, purpose and related standards In addition to the following, Chapter 1 of the general standard 1) applies: 201:1:1 *Scope replace: This section applies to the basic safety and basic performance of surgical shadowless lamps and diagnostic lighting (hereinafter referred to as ME equipment): This section does not apply to

--- GB 9706:19 involves endoscopes, laparoscopes and their light sources;

--- YY/T 1120 related dental lighting;

---GB 7000:201 and GB 7000:204 related general lamps;

---Therapeutic lamp;

---Special light sources with special purposes, such as ultraviolet light for dermatological diagnosis, ophthalmic slit lamps, surgical microscope lights, and surgical navigation systems All lights;

---Lights connected with surgical instruments;

--- Emergency lighting related to GB 7000:2: Note: See 4:2 of the general standard: 201:1:2 Purpose replace: The purpose of this part is to specify the basic safety and basic performance of surgical shadowless lamps and diagnostic lamps that meet the definition of:201:3: Claim: 201:1:3 Specific standards replace: In the GB 9706:1 series of standards, special standards can be modified, replaced or deleted according to the conditions of special ME equipment: The requirements listed in the standards can add other basic safety and basic performance requirements: The requirements of specific standards take precedence over the requirements of general standards: For simplicity, in this section, GB 9706:1 is referred to as "General Standard": The numbering method of clauses and subclauses in this part conforms to the numbering method of clauses in the general standard and is prefixed with "201" (as in this part 201:1 describes the content of Chapter 1 of the General Standard), or conforms to the numbering method of the clauses in the applicable parallel standard with the prefix "20X", which The X refers to the last number of the parallel standard document number (for example, 202:4 in this part explains the internal part of Chapter 4 of the IEC 60601-1-2 parallel standard): Content, 203:4 of this part describes the content of Chapter 4 of the 60601-1-3 parallel standard, and so on: By using the following word pair and general standard The content-related changes are stipulated: 1) General standards refer to GB 9706:1, "Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Basic Performance":

1 Scope

YY 9706.241 is the mandatory Chinese standard for surgical and diagnostic luminaires, the operating theatre lights designed to illuminate a cavity without casting the surgeon's own shadow into it. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the illuminance at the surgical site and its depth, the shadow dilution that gives the light its name, the colour rendering that lets tissue be distinguished, the radiant heat delivered into an open wound, and the mechanical stability of the suspension arm. A light that fails mid-operation stops the operation. It replaces YY 0627-2008 and took effect in May 2023.