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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.257-2021

Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic or aesthetic use

医用电气设备 第2-57部分：治疗、诊断、监测和整形医疗美容使用的非激光光源设备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.

This Part is mandatory for the full text. "Medical electrical equipment" is divided into two parts. - Part 1: General requirements for the basic safety and essential performance; - Part 2: Particular requirements for the basic safety and essential performance. This Part is "Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use". This Part was drafted in accordance with the rules given in GB/T 1.1-2009. This Part adopts the redrafting method to amend IEC

60601-2-57.2011 "Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use". There are technical differences between this Part and IEC 60601-2-57.2011, and the clauses involved in these differences have been marked by a vertical single line (|) in the position of the outer margin. The technical differences between this Part and IEC 60601-2-57.2011 and their reasons are as follows. - Regarding normative references, this Part has made adjustments with technical differences to adapt to the technical conditions of China. The adjustments are concentrated in "201.2 Normative references", and the specific adjustments are as follows. - REPLACE ISO 3864-2 with GB/T 2893.2, which is amended form the international standard; - REPLACE IEC 62471 with GB/T 20145, which is identical to the international standards; - REPLACE IEC 60947-3 with GB/T 14048.3, which is identical to the international standard. For ease of use, for IEC 60601-2-57.2011, this Part has made the following editorial changes. - DELETE the note in 201.3 about the index of terms and definitions; - AMEND 202.102 in 201.6.1.102.2

b) TO 201.102, which is an editorial error. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights. This Part was proposed by the National Medical Products Administration. This Part shall be under the jurisdiction of Sub-Technical Committee on Medical Optics and Instrument of Standardization Administration of China (SAC/TC 103/SC 1). Drafting organization of this Part. Zhejiang Institute of Medical Device Testing. Main drafters of this Part. Ye Yueshun, Li Min, Du Kun, Fang Chunzi. Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use 201.1 Scope, object and related standards Clause 1 of the general standard applies, except as follows. 201.2 Normative references The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. 201.3 Terms and definitions For the purposes of this document, the terms and definitions given in GB 9706.1, apply, except as follows: Replacement. 201.4 General requirements Clause 4 of the general standard applies. 201.5 General requirements for testing ME EQUIPMENT Clause 5 of the general standard applies. 201.6 Classification of ME EQUIPMENT and ME SYSTEMS Clause 6 of the general standard applies, except as follows. 201.7 ME EQUIPMENT identification, marking and documents Clause 7 of the general standard applies, except as follows. 201.8 Protection against electrical HAZARDS from ME EQUIPMENT Clause 8 of the general standard applies, except as follows. 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS Clause 9 of the general standard applies. 201.10 Protection against unwanted and excessive radiation HAZARDS Clause 10 of the general

standard applies except as follows. 201.11 Protection against excessive temperatures and other HAZARDS Clause 11 of the general standard applies. 201.12 Accuracy of controls and instruments and protection against hazardous outputs Clause 12 of the general standard applies, except as follows. 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) Clause 14 of the general standard applies. 201.15 Construction of ME EQUIPMENT Clause 15 of the general standard applies. 201.16 ME SYSTEMS Clause 16 of the general standard applies. 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS Clause 17 of the general standard applies. .....

1 Scope

YY 9706.257 is the mandatory Chinese standard for non-laser light source equipment used therapeutically, diagnostically and cosmetically: intense pulsed light systems, LED phototherapy, and the aesthetic devices sold in enormous numbers into Chinese clinics and salons. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the optical output and its spectrum, the exposure limits that protect skin and eyes, the filters and interlocks, and the information that has to be given to an operator who may not be a clinician. Cosmetic light devices are the part of this class where harm is most often reported and least often reported to a regulator. Being a YY standard without the /T suffix, compliance is compulsory. It took effect in May 2023.