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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 9706.258-2022

Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

医用电气设备 第2-58部分：眼科手术用晶状体摘除及玻璃体切除设备的基本安全和基本性能专用要求

Issued on: May 18, 2022 **Implemented on: June 1, 2025**

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Foreword

This document was issued on 18 May 2022 by the National Medical Products Administration and takes effect on 1 June 2025.

It is a YY standard without the /T suffix: compliance is mandatory in China.

This document was drafted in accordance with the rules given in GB/T 1.1-2020 "Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents". The "Medical electrical equipment" series of standards is divided into two parts. - Part 1: General and parallel requirements; - Part 2: Particular requirements. This document is Part 2-58 of YY 9706 "Medical electrical equipment". This document uses

redrafting method to modify and adopt IEC 80601-2- 58.2014+Amd 1.2016 "Medical electrical equipment

-- Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery".

Compared with IEC80601-2-58.2014+Amd1.2016, this document has undergone the following structural adjustments. - 202.5.2.2.3 corresponds to 202.5.2.2 in IEC 80601-2-58.2014+Amd1.2016; - 202.5.2.2.6 corresponds to 202.5.2.2.4 in IEC 80601-2-58.2014+Amd1.2016; - 202.6.1.1 corresponds to 202.7 in IEC 80601-2-58.2014+Amd1.2016; - 202.6.2.10 corresponds to 202.8 in IEC 80601-2-58.2014+Amd1.2016. The technical differences between this document and IEC 80601-2- 58.2014+Amd1.2016, and the reasons therefor, are as follows. - Regarding normative references, this document has been revised to reflect technical differences, so as to adapt to Chinese technical conditions. The specific revisions are reflected in "201.2 Normative references". The specific revisions are as follows. * CISPR 11 has been replaced by GB 4824-2019, which is equivalent to CISPR 11; * IEC 60601-1-2 has been replaced by YY 9706.102-2021, which modifies and adopts IEC 60601-1-2; * IEC 60601-2-2 has been replaced by GB 9706.202, which modifies and adopts IEC 60601-2-2; * IEC 60601-2-22 has been replaced by GB 9706.20, which is equivalent to IEC Medical electrical equipment

-- Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery 201.1 Scope, purpose and related standards Except as described below, Chapter 1 of the General Standard applies. 201.1.1 * Scope Replacement.

This document specifies the basic safety and performance requirements for ophthalmic surgical lens removal and vitrectomy device. This document applies to the basic safety and performance of ophthalmic surgical lens removal and vitrectomy device, as well as related accessories that can be connected to such medical electrical equipment. If a clause or sub-clause applies only to medical electrical equipment or only to medical electrical systems, this will be stated in the heading and content of that clause or sub- clause. If this is not the case, then the clause or sub-clause applies to both medical electrical equipment and medical electrical systems. This document does not cover hazards inherent in the intended physiological function of medical electrical equipment or systems within its scope, except for 7.2.13 and 8.4.1 of the General Standard. NOTE. See 4.2 of the General Standard. 201.1.2 Purpose Replacement. The purpose of this document is to establish specific safety requirements for ophthalmic surgical lens removal and vitrectomy devices, as well as related accessories that can be connected to the devices and tested together or separately. 201.1.3 * Parallel standards .....

1 Scope

YY 9706.258 is the mandatory Chinese standard for phacoemulsification and vitrectomy

equipment, the machines that remove a cataractous lens or the vitreous gel through incisions a few millimetres wide. It sets the particular requirements for basic safety and essential performance on top of the general medical electrical safety standard, covering the aspiration and irrigation that keep the eye inflated while material is removed, the ultrasound or cutting energy delivered, and the behaviour when a surge or an occlusion break occurs. A momentary collapse of the anterior chamber during phaco can tear the capsule and change the outcome of the operation. Cataract surgery is the highest-volume operation in Chinese ophthalmology. Being a YY standard without the /T suffix, compliance is compulsory. It takes effect in June 2025.