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Silicone rubber compounds for medical catheters

硅橡胶混炼胶 医疗导管用

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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 for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the right to identify patents. This document was proposed by the China Petroleum and Chemical Industry Federation. This document is under the jurisdiction of the National Technical Committee on Rubber and Rubber Products (SAC/TC35). This document was drafted by: Jiangxi Bluestar Spark Organic Silicone Co., Ltd., Yongxiu County Inspection and Testing Center (Jiangxi Organic Silicone Product Quality Supervision Center Supervision and Inspection Center), Guangdong Yikang Medical Equipment Co., Ltd., Dongguan Zhengan Silicone Technology Co., Ltd., Dongguan Ruixiang Precision Silicone Products Co., Ltd., Jinan Chensheng Medical Technology Co., Ltd., Henan Jianqi Medical Equipment Co., Ltd., Dongguan Pinsheng Silicone Technology Co., Ltd. Dongguan Nanju Polymer Materials Co., Ltd., Shenzhen Baoan Medical Supplies Co., Ltd., Guangzhou Ruipai Medical Equipment Co., Ltd., Shenyang Rubber Research and Design Institute Co., Ltd. The main drafters of this document are. Yu Liang, Gao Hongkai, Wu Hong, Wu Chaobo, Chen Hao, Liao Quangen, Zhao Lingzhi, Liang Zhijun, Ren Baolai, Chen Sanling, Luo Hongkun, Xu Yannan, Wu Hao, He Shaofeng, and Liu Jiaxin. Silicone rubber compound for medical catheters

1 Scope

China's national standard for silicone rubber compounds used in medical catheters. Silicone is the material for catheters that stay in the body because of a combination nothing else matches: it is inert enough to provoke little tissue response, remains flexible across the

temperature and time it is exposed to, tolerates steam and radiation sterilisation, and can be moulded or extruded into thin-walled tubing with the softness that makes a catheter tolerable to the patient. The compound is what determines all of it - the base polymer, the reinforcing silica, the catalyst system, and above all the residual volatiles and extractables, since anything that can leach out of the material will do so into tissue. The standard applies to compounds for catheters in temporary and short-term contact, which are Class II medical devices under China's classification rules, and specifies naming, technical requirements, test methods, inspection rules, marking, packaging, transport and storage.

This document specifies the naming, technical requirements, inspection rules and marking, packaging, transportation and storage of silicone rubber compounds for medical catheters. The corresponding test methods are described. This document applies to the preparation of silicone rubber compounds (hereinafter referred to as compounds) for temporary and short-term contact medical catheters.

Note. According to the "Medical Device Classification Rules", the medical catheters in this document belong to Class II medical devices.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 528 Determination of tensile stress-strain properties of vulcanized rubber or thermoplastic rubber

GB/T 529 Determination of tear strength of vulcanized rubber or thermoplastic rubber (trouser-shaped, right-angled and crescent-shaped test specimens)

GB/T 531.1 Test method for indentation hardness of vulcanized rubber or thermoplastic rubber Part

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Naming

According to the provisions of GB/T 32365, silicone rubber is named by category code, hardness and use symbol. Example. A silicone rubber compound for medical catheters with a hardness of

40 Shore A is named. VMQ40-M VMQ 40-M Silicone rubber category code hardness

Medical type

5 In vitro cytotoxicity test

GB/T 16886.6 Biological evaluation of medical devices Part

6 Local reaction test after implantation

GB/T 16886.10 Biological evaluation of medical devices Part

10 Skin sensitization test

GB/T 16886.11 Biological evaluation of medical devices Part

11 Systemic toxicity tests

GB/T 28112 Determination of volatile methylcyclosiloxane residues in silicone rubber

GB/T 32365 Classification and systematic nomenclature of silicone rubber compounds