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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 19701.3-2024

**Implants for surgery - Ultra-high-molecular-weight polyethylene
- Part 3: Accelerated ageing methods**

外科植入物 超高分子量聚乙烯 第3部分：加速老化方法

(English Translation)

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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.

This document is part 3 of GB/T 19701 Ultra-high molecular weight polyethylene for surgical implants. GB/T 19701 has been published the following parts.

- Part 1: Powders;
- Part 2: Moulding materials;
- Part 3: Accelerated aging methods;
- Part 5: Morphological evaluation method.

This document is modified to adopt ISO 5834-3:2019 "Ultra-high molecular weight polyethylene for surgical implants - Part 3: Accelerated ageing methods".

This document has the following structural adjustments compared to ISO 5834-3:2019.

---11.2~11.5 correspond to 11.1~11.4 in ISO 5834-3:2019.

The technical differences between this document and ISO 5834-3:2019 and their reasons

are as follows.

--- ISO 5834-2 (see Chapter 4 and Chapter 5) has been replaced by the normative reference GB/T 19701.2 to adapt to the technical requirements of my country.

Improve operability;

--- The normative reference GB/T 21461.1 replaces ISO 11542-1 (see Chapter 3) to adapt to my country's technical conditions and provide High operability;

--- ISO 11542-2 (see Chapter 3) has been replaced by the normative reference GB/T 21461.2 to adapt to my country's technical conditions and provide High operability;

--- ASTM F.2003..2015 was replaced by the normatively referenced ASTM F.2003.2022 (see Chapters 6 to 8, Chapter 10 Chapter), due to the updated version of the referenced standard.

The following editorial changes were made to this document.

--- Replaced the informative reference ISO 14242 (all parts) with YY/T 0651 (all parts) (see Chapter 9);

--- Replaced the informative reference ISO 14243 (all parts) with YY/T 1426 (all parts) (see Chapter 9).

Introduction

Ultra-high molecular weight polyethylene has good mechanical properties, wear resistance and biocompatibility, and is widely used in surgical implants such as artificial joints, Widely used in scaffold products.

GB/T 19701 "Ultra-high molecular weight polyethylene for surgical implants" is planned to consist of 5 parts.

--- Part 1: Powders. The purpose is to standardize the requirements and corresponding tests of ultra-high molecular weight polyethylene powders for surgical implants method.

--- Part 2: Moulding materials. The purpose is to specify the requirements and related the method should be tested.

--- Part 3: Accelerated aging method. The purpose is to provide ultra-high molecular weight polyethylene (UHMWPE) materials for surgical implants Test method for oxidative stability during processing and sterilization.

--- Part 4: Oxidation index test method. The purpose is to provide a test method for the relative oxidation degree of ultra-high molecular weight polyethylene.

Evaluation of the relative degree of oxidation of ultra-high molecular weight polyethylene.

--- Part 5: Morphology evaluation method. The purpose is to provide a morphology quality

test method for ultra-high molecular weight polyethylene molding compounds to evaluate Relative cure qualities (morphology) of ultra-high molecular weight polyethylene molding compounds.

Ultra-high molecular weight polyethylene for surgical implants Part 3: Accelerated aging methods

1 Scope

This document describes the oxidative stability of ultra-high molecular weight polyethylene (PE-UHMW) materials for surgical implants during processing and sterilization.

test method.

This document describes a method for accelerated aging of PE-UHMW specimens and components for total joint prostheses.

The materials were aged under conditions to accelerate oxidation and thus assess their potential long-term chemical and mechanical stability.

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 19701.2 Ultra-high molecular weight polyethylene for surgical implants Part 2: Moulding materials (GB/T 19701.2-2024, ISO 5834-2:2019,MOD) GB/T 21461.1 Plastics Ultra-high molecular weight polyethylene (PE-UHMW) molding and extrusion materials Part 1: Nomenclature system and Classification basis (GB/T 21461.1-2023, ISO 21304-1:2019, MOD) GB/T 21461.2 Plastics Ultra-high molecular weight polyethylene (PE-UHMW) molding and extrusion materials Part 2: Sample preparation and Performance measurement (GB/T 21461.2-2023, ISO 21304-2:2021, MOD) ASTM F2003:2022 Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma-Ray Irradiation in Air tioninAir)

3 Terms and definitions

The terms and definitions defined in GB/T 21461.1, GB/T 21461.2 and the following apply to this document.

The terminology databases used for standardization maintained by ISO and IEC are located at.

Oxidation

Oxygen is introduced into the molecule [eg, ultra-high molecular weight polyethylene (PE-UHMW)] via chemical covalent bonds.

4 Categories

The test samples for accelerated aging should be made of Type 1, Type 2 or Type 3 PE-UHMW molding compounds specified in GB/T 19701.2.

manufacture.

NOTE: Type 3 polymers are no longer manufactured. However, to cover existing reserves in inventory, Type 3 material is retained in this document until the next revision.