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

GB/T 19701.1-2024

**Implants for surgery - Ultra-high-molecular-weight polyethylene
- Part 1: Powder form
(English Translation)**

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Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives

for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This document is Part 1 of GB/T 19701 Implants for Surgery - Ultra-high-molecular-weight Polyethylene. GB/T 19701 has issued the following parts.

---Part 1.Powder form;

---Part 2.Moulded forms;

---Part 3.Accelerated ageing methods;

---Part 5.Morphology assessment method.

This document serves as a replacement for GB/T 19701.1-2016 Implants for Surgery - Ultra-

high-molecular-weight Polyethylene - Part 1.Powder Form. In comparison with GB/T 19701.1-2016, apart from structural adjustments and editorial modifications, the main

technical

changes are as follows.

---The reference Standard of the test method for stress at definite elongation is modified (see 8.1; 8.1 of Version 2016);

---The reference Standard of the test method for viscosity is modified (see 8.2; 8.2 of Version 2016);

---The reference Standard of the test method for ash content is modified (see 8.3; 8.3 of Version 2016);

---The reference Standard of the test report is added [see Chapter 9 a)].

This document modifies and adopts ISO 5834-1:2019 Implants for Surgery - Ultra-high-molecular-weight Polyethylene - Part 1. Powder Form.

The technical differences between this document and ISO 5834-1:2019, and the causes for the

differences are as follows.

---The normative reference GB/T 21461.1 is used to replace ISO 11542-1 (see Chapter 3), so as to adapt to the technical conditions of China and enhance the operability;

---The normative reference GB/T 21461.2 is used to replace ISO 11542-2 (see Chapter 3, 8.1), so as to adapt to the technical conditions of China and enhance the operability;

---The normative reference GB/T 1632.3 is used to replace ISO 1628-3 (see 8.2), so as to adapt to the technical conditions of China and enhance the operability;

Implants for Surgery - Ultra-high-molecular-weight

Polyethylene - Part 1. Powder Form

1 Scope

This document specifies the requirements for ultra-high-molecular-weight polyethylene (PE-UHMW) powders for surgical implants and describes the corresponding test methods.

This document does not apply to products made from powders.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only

versions with a specified date are applicable to this document. In terms of references without a

specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 1632.3 Plastics - Determination of the Viscosity of Polymers in Dilute Solution Using Capillary Viscometer - Part 3.Polyethylenes and Polypropylenes (GB/T 1632.3-2010, ISO 1628-3.2001, MOD)

GB/T 9345.1 Plastics - Determination of Ash - Part 1.General Methods (GB/T 9345.1-2008, ISO 3451-1.1997, IDT)

GB/T 21461.1 Plastics - Ultra-high-molecular-weight Polyethylene (PE-UHMW) Moulding and Extrusion Materials - Part 1.Designation System and Basis for Specifications (GB/T 21461.1-2023, ISO 21304-1.2019, MOD)

GB/T 21461.2 Plastics - Ultra-high-molecular-weight Polyethylene (PE-UHMW) Moulding and Extrusion Materials - Part 2.Preparation of Test Specimens and Determination of Properties (GB/T 21461.2-2023, ISO 21304-2.2021, MOD)

DIN 53474 Testing of Plastics, Rubber and Elastomers - Determination of the Chlorine Content

(Wickbold-combustion)

3 Terms and Definitions

The terms and definitions defined in GB/T 21461.1 and GB/T 21461.2 are applicable to this document.

The URLs of the terminology databases for standardization maintained by ISO and IEC are as

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