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

GB/T 19701.2-2024

**Implants for surgery - Ultra-high-molecular-weight polyethylene
- Part 2: Moulded forms
(English Translation)**

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document is Part 2 of GB/T 19701 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene. GB/T 19701 has published in the following parts.

- Part 1.Powder Forms;
- Part 2.Moulded Forms;
- Part 3.Accelerated Aging;
- Part 5.Morphology.

This Document replaced GB/T 19701.2-2016 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 2.Moulded Forms. Compared with GB/T 19701.2-2016, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications.

- Delete the requirements and test methods for ash content (see Table 1, 7.3 of the 2016 Edition);
- Change the requirements for tensile breaking stress and elongation at break for Type 1 and Type 2 ultra-high-molecular-weight polyethylene molding compounds (see Table 1 of this Edition; Table 1 of the 2016 Edition).
- Delete the requirements and test methods for double-notched impact strength (see Table 1, 7.7 of the 2016 Edition);
- Change the method for calculating the sampling area of particulate matter (see 8.5 of this Edition; 7.8 of the 2016 Edition).

This Document modified and adopted ISO 5834-2:2019 Implants for Surgery - Ultra-High-Molecular-Weight Polyethylene - Part 2: Moulded Forms.

The technical differences and their causes between this Document and ISO 5834-2:2019 are as follows.

- Replace ISO 5834-1 (see Clauses 4 and 5) with the normatively referenced GB/T 19701.1 to adapt to China's technical conditions and improve operability;
- Change the clauses concerning test conditions involved conditioning in subclause 8.1 from "8.2~8.5" to "8.2~8.4". Subclause 8.5 states that the above conditioning is not required before the sampling area test for particulate matter.

Implants for Surgery - Ultra-High-Molecular-Weight
Polyethylene - Part 2: Moulded Forms

1 Scope

This Document specifies the requirements for ultra-high molecular weight polyethylene (PE-UHMW) molding compounds (such as sheets and rods) used in surgical implants; and describes the corresponding test methods.

This Document applies to ultra-high molecular weight polyethylene (PE-UHMW) molding

compounds.

This Document does not apply to products that are directly molded (near the final form), irradiated products, or final products, nor to products made from polyethylene containing additives or blends of different types of polyethylene.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates

indicated are applicable to this Document; for the undated documents, only the latest version

(including all the amendments) is applicable to this Document.

GB/T 19701.1 Surgical implants - Ultra-high-molecular-weight polyethylene - Part 1. Powder form (GB/T 19701.1-2024, ISO 5834-1.2019, MOD)

ISO 1183-1 Plastics - Methods for determining the density of non-cellular plastics - Part 1.

Immersion method, liquid pycnometer method and titration method

NOTE: GB/T 1033.1-2008 Plastics -- Methods for determining the density of non-cellular plastics -- Part

1 Immersion method, liquid pycnometer method and titration method (ISO 1183-1.2004, IDT)

ASTM F648 Standard specification for ultra-high-molecular-weight polyethylene powder and

fabricated from for surgical implants

3 Terms and Definitions

For the purposes of this Document, there are no terms and definitions apply.

4 Classification

Materials for molding compound production according to Type 1, Type 2, and Type 3 powders

as defined in GB/T 19701.1 are correspondingly classified as Type 1, Type 2, and Type 3

molding compounds.

5 Materials

The molding compounds shall be molded from PE-UHMW powder meeting the requirements

of GB/T 19701.1.

6 Manufacturing Requirements

Each molding compound order shall be traceable to its manufacturing process, such as batch

number.

Molding compounds may undergo stress-relief annealing according to the agreement between

the supplier and the purchaser.

During the molding process, to avoid contamination, migration, and molding defects, liquid or

powdered release agents (such as those with silicone or talc as the main component) shall not

be used.

7.1 Physical properties

When tested according to the test methods in Table 1, the physical properties of the molding

compounds shall conform to the corresponding given values for each material category in Table

1.

Given that subsequent manufacturing processes may affect the comparability of test results, the

physical properties of the cured and annealed materials shall be tested before further processing.

7.2 Particulate matter

Samples prepared and inspected according to 8.5 shall have a surface visible particle count not