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**Implants for surgery — Ultra-high-molecular-weight polyethylene —**

**Part 2:  
Moulded forms**

*Implants chirurgicaux — Polyéthylène à très haute masse moléculaire — Partie 2: Produits sous forme moulée*



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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5834-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fourth edition cancels and replaces the third edition, which has been technically revised.

ISO 5834 consists of the following parts, under the general title *Implants for surgery — Ultra-high-molecular-weight polyethylene*:

- Part 1: Powder form
- Part 2: Moulded forms
- Part 3: Accelerated ageing methods
- Part 4: Oxidation index measurement method
- Part 5: Morphology assessment method



# Implants for surgery — Ultra-high-molecular-weight polyethylene —

## Part 2: Moulded forms

### 1 Scope

This part of ISO 5834 specifies the requirements and corresponding test methods for moulded forms, e.g. sheets and rods, made from ultra-high-molecular-weight polyethylene (UHMWPE) for use in the manufacture of surgical implants.

This part of ISO 5834 is not applicable to direct-moulded (near net shape), irradiated or finished products or products manufactured from polyethylene blended with additives or by blending different forms of polyethylene.

### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 1183-1:—<sup>1)</sup>, *Plastics — Methods for determining the density of non-cellular plastics — Part 1: Immersion method, liquid pycnometer method and titration method*

ISO 3451-1:2008, *Plastics — Determination of ash — Part 1: General methods*

ISO 5834-1, *Implants for surgery — Ultra-high-molecular-weight polyethylene — Part 1: Powder form*

ISO 11542-2:1998, *Plastics — Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials — Part 2: Preparation of test specimens and determination of properties*

### 3 Classification

The material moulded from Type 1, Type 2 or Type 3 powder as defined in ISO 5834-1 shall be classified as Type 1, Type 2 or Type 3 respectively.

### 4 Material

The moulded material shall be made from UHMWPE powder in accordance with the requirements of ISO 5834-1.

### 5 Manufacturing requirements

The moulded material supplied for each order shall be identified by lot numbers.

NOTE “Lot” refers to the material for which testing has been carried out and for which discrete records are kept.

The material shall be subjected to a stress-relief annealing process as agreed by the purchaser and the vendor.

1) To be published (revision of ISO 1183-1:2004).