



Designation: F2848 – 17

Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns¹

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1. Scope

1.1 This specification covers ultra-high molecular weight polyethylene (UHMWPE) yarns intended for use in medical devices or components of medical devices, such as sutures and ligament fixations. This specification covers natural (non-colored) and pigmented (colored) yarns.

1.2 This standard is intended to describe the requirements and the procedures to be followed for testing UHMWPE yarns as a component for medical devices prior to manufacturing processes of the medical device such as fabric formation, assembling and sterilization. This specification does not purport to address the requirements for the finished medical devices or the testing that is needed for medical devices that are fabricated from the components specified herein.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

- D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
- D885/D885M Test Methods for Tire Cords, Tire Cord Fabrics, and Industrial Filament Yarns Made from Manufactured Organic-Base Fibers
- D1505 Test Method for Density of Plastics by the Density-Gradient Technique
- D1601 Test Method for Dilute Solution Viscosity of Ethylene Polymers
- D1907/D1907M Test Method for Linear Density of Yarn (Yarn Number) by the Skein Method
- D2256/D2256M Test Method for Tensile Properties of Yarns by the Single-Strand Method
- F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
- F756 Practice for Assessment of Hemolytic Properties of Materials
- F2625 Test Method for Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point of Ultra-High-Molecular Weight Polyethylene by Means of Differential Scanning Calorimetry
- 2.2 ISO Standards:³
- ISO 1628-3 Plastics—Determination of the Viscosity of Polymers in Dilute Solution Using Capillary Viscometers—Part 3: Polyethylenes and Polypropylenes
- ISO 2062 Textiles—Yarns from Packages—Determination of Single-end Breaking Force and Elongation at Break
- ISO 10993-1 Biological Evaluation of Medical Devices Part 1 – Evaluation and testing within a risk management process
- ISO 10993-4 Biological Evaluation of Medical Devices Part 4 – Selection of tests for interactions with blood
- ISO 10993-5 Biological Evaluation of Medical Devices Part 5 – Tests for in vitro cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-17 Biological Evaluation of Medical Devices Part 17 – Establishment for allowable limits for leachable substances

³ Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

TABLE 1 Requirements for UHMWPE Yarns

Property	Test Method	Requirement
Density, g/cm ³	Test Methods D792 or D1505	0.95 - 1.00
Melting temperature – peak, °C	Test Method F2625	140 - 150
Filament Linear Density, dtex (Maximum)	6.3	2.7
Intrinsic Viscosity, dl/g (Minimum)	6.4	15
Tensile Strength, cN/dtex (Minimum)	6.5	26
Tensile Modulus, cN/dtex (Minimum)	6.5	750
Elongation-at-break, %	6.5	2 - 5
<i>Additional requirement for colored yarn:</i>		
Pigment content, wt.% (Maximum)	6.2	2
Chromium-cobalt-aluminum oxide		

ISO 8 Biological Evaluation of Medical Devices Part 18 – Chemical characterization of materials

ISO 13485 Medical Devices – Quality Management Systems – Requirements for regulatory purposes

ISO 14971 Medical Devices – Application of risk management to Medical Devices

2.3 *Other Documents:*

ICH Q3C(R3) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Impurities: Residual Solvents⁴

US Code of Federal Regulations—CFR section 21 Parts 70, 71, 73, 74 and 80 on color additives for medical devices⁵

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *UHMWPE filament*—molecularly oriented highly crystalline fiber spun from virgin UHMWPE polymer powder.

3.1.2 *UHMWPE yarn*—a continuous strand of more than one UHMWPE filaments in a form suitable for operations such as weaving, knitting, etc.

3.1.3 *linear density*—mass per length, expressed in dtex (mass in grams per 10 000 metres).

3.1.3.1 *Discussion*—Tex is a unit of measure for the linear mass density of yarns and is defined as the mass in g/1000 m. Because of the low mass of yarns used in medical applications, decitex (abbreviated as dtex) is more commonly used, and is mass in g/10 000 m. Another related unit of measure for the linear mass density is denier, which is defined as g/9000 m.

3.1.4 *production liquid*—any liquid(s) used in the production of the filaments and yarns, such as solvents and extraction solutions.

4. UHMWPE Filament and Yarn Requirements

4.1 *Compositional Requirements:*

4.1.1 Maximum acceptable limits for residual constituents shall be determined based on prevention of adverse effects when used in a medical application (see also 4.4). Residual

constituents can be residues from the used production liquids, processing aids, or residual elements from raw materials.

4.1.2 Residual production liquids shall be assessed with regard to toxicity hazards, with a maximum acceptable limit consistent with ICH Q3C(R3). If no ICH concentration guideline has been established for a utilized production liquid, a toxicity assessment and corresponding potential leaching characteristics for the identified potential toxic ingredients should be performed in accordance with 4.4 to establish a maximum residual level.

4.1.3 Potential effects of residual production liquid(s) on mechanical or physical yarn properties should be considered as well for establishing maximum limits.

4.1.4 For decalin as solvent, the residual level has been established in accordance with 4.4 and 4.1.3 and shall be less than 100 mg/kg (see 6.1).

4.1.5 In case a color additive or pigment is added to the yarn, this should be compliant to the FDA regulation as published in the US Code of Federal Regulations - CFR section 21, parts 70, 71, 73, 74 and 80 on color additives for medical devices.

4.2 *Physical Requirements:*

4.2.1 The density of the yarn shall comply with the requirement listed in Table 1.

4.2.2 The linear density requirement of single filaments is listed in Table 1.

4.2.3 The intrinsic viscosity requirement for the UHMWPE yarn is listed in Table 1.

4.3 *Mechanical Requirements:*

4.3.1 Tensile testing shall be conducted after sufficient conditioning to the laboratory conditions, with a minimum of 2 h to achieve uniform temperatures within the yarn package.

4.3.2 UHMWPE yarns shall meet the tensile requirements on strength, modulus, and elongation-at-break as listed for individual data as listed in Table 1. Note that tensile properties of the final medical device depend on the construction of yarns used therein.

4.4 *Biocompatibility and Biosafety Risk Assessment Requirements:*

4.4.1 The first principle of ISO 10993-1 states that biological evaluation of any material or medical device intended for use in humans shall form part of a structured biological evaluation program within a risk management process in accordance with ISO 14971. This should be addressed through chemical characterization of the material, following ISO

⁴ Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, c/o IFPMA, 15 ch. Louis-Dunant, P.O. Box 195, 1211 Geneva 20, Switzerland, <http://www.ich.org>.

⁵ U.S. Government Publishing Office, 710 North Capitol Street N.W., Washington, DC (corner of North Capitol and H Streets), www.gpo.gov/about/bookstore.htm