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.

Designation: F2848 – 21

Standard Specification for Medical-Grade Ultra-High-Molecular-Weight Polyethylene Yarns[1]

This standard is issued under the fixed designation F2848; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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, health, and environmental 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]

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

D5630 Test Method for Ash Content in Plastics

D8171 Test Methods for Density Determination of Flax Fiber

E1131 Test Method for Compositional Analysis by Thermogravimetry

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

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 processs

ISO 10993-4 Biological Evaluation of Medical Devices—Part 4: Selection of tests for interactions with blood

[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.

[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.

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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
ISO 10993-18 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 Solvents[4]
U.S. Code of Federal Regulations—CFR Section 21 Parts 70, 71, 73, 74, and 80 on color additives for medical devices[5]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.1.1 *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.

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

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

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

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 U.S. Code of Federal Regulations—CFR Section 21, Parts 70, 71, 73, 74, and 80 on color additives for medical devices.

4.1.5.1 In case a chromium-cobalt-aluminum oxide color additive or pigment is added to the yarn, this should be compliant to the FDA regulation as published in the U.S. Code of Federal Regulations—21 CFR 73.1015 on color additives for medical devices.

4.1.5.2 In case a black color additive or pigment is added to the yarn, this should be compliant to the FDA regulation as published in the U.S. Code of Federal Regulations—21 CFR 74.3054 which provides requirements for the safe use of D&C Black No. 4 for coloring UHMWPE surgical sutures.

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] 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

TABLE 1 Requirements for UHMWPE Yarns

Property	Requirement	Test Method
Density, g/cm^3	0.95–1.00	See 6.6
Melting temperature – peak, °C	140–150	Test Method F2625
Filament Linear Density, dtex (Maximum)	2.7	See 6.3
Intrinsic Viscosity, dl/g (Minimum)	15	See 6.4
Tensile Strength, cN/dtex (Minimum)	26	See 6.5
Tensile Modulus, cN/dtex (Minimum)	750	See 6.5
Elongation-at-break, %	2–5	See 6.5
Additional requirement for colored yarn:		
Pigment content, wt.% (Maximum)		
Chromium-cobalt-aluminum oxide	2	See 6.2
D&C Black No. 4	1.0	See 6.7