EC DECLARATION OF CONFORMITY

Legal Manufacturer Name and Address:	Teleflex Medical 3015 Carrington Mill Boulevard Morrisville, NC 27560 USA
Authorized Representative Name and Address:	Teleflex Medical IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath, Ireland
Notified Body Name and Address:	☐ *Class I: Not Applicable* ☒ *Class Is, Im, IIa, IIb, III* SGS United Kingdom, Ltd. Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS22 0WA, U.K. CE 0120

☐ **Class I**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex *Insert Annex Number* and *Insert Version (ISO, BSI BS EN ISO, etc.)* ISO 13485:*Insert Publication Date*, as implemented by the European Union's Medical Devices Regulations.

☒ **Class Is, Im, IIa, IIb, III**

Teleflex Medical declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC dated 14, June 1993 as amended by 2007/47/EC and is in accordance with Annex II (excluding section 4) and ISO 13485:2016, EN ISO 13485:2016, as implemented by the European Union's Medical Devices Regulations as verified by the Notified Body listed above:

Teleflex Medical confirms that no other application has been lodged with another Notified Body for the same devices related Quality Management System.

Teleflex Medical agrees to develop, implement, and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Teleflex Medical agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Teleflex Medical confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Teleflex Medical agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, if applicable.

Product Name:	**Force Fiber® Non-Absorbable Surgical Suture**
Classification:	**Class IIb Rule 8**
EC Certificates No.:	**European – ISO 13485: 2016, EN ISO 13485: 2016 – US97/10878.00, .01, .02** **European – 93/42/ECC- US97/10879.00, .01, .02** **MDSAP (ISO 13485:2016) – US18/81827522**
Conformity Assessment Routes:	**Annex II (excluding section 4) of the MDD (93/42/EEC), Full Quality Assurance System**

Product Code	Trade Name	Product Description	Size	Needle	QTY	Company	CE Distribution Date	GMDN Code
900244	MaxBraid	Surgical Suture, Blue Co-Braid	4-0, 18"	T1, 1N	12	OEM: Biomet	Jan-09	13907
900252	MaxBraid	Surgical Suture, Blue Co-Braid	3-0, 18"	T-2, 1N	12	OEM: Biomet	Jan-09	13907
900267	MaxBraid	Surgical Suture, Blue Co-Braid	0, 38"	T-2, 1N	12	OEM: Biomet	Jan-09	13907
900284	MaxBraid	Surgical Suture, Blue Co-Braid	2, 38"	KHC-5, 1N	12	OEM: Biomet	Jan-09	13907
900285	MaxBraid	Surgical Suture, Blue Co-Braid	2, 38"	KHC-5, 1N	1	OEM: Biomet	Jan-09	13907
900312	MaxBraid	Surgical Suture, Blue Co-Braid	5, 38"	K-60, 1N	12	OEM: Biomet	Jan-09	13907
900333	MaxBraid	Surgical Suture, White Braid	2, 38"	HC-5, 1N	12	OEM: Biomet	Feb-05	13907
900334	MaxBraid	Surgical Suture, Blue Co-Braid	2, 38"	HC-5, 1N	12	OEM: Biomet	Feb-05	13907
900335	MaxBraid	Surgical Suture, Blue Co-Braid	2, 38"	C-7, 1N	12	OEM: Biomet	Feb-05	13907
900336	MaxBraid	Surgical Suture, Blue Co-Braid	2-0, 24"	AT-2, 1N	12	OEM: Biomet	Feb-05	13907
900338	MaxBraid	Surgical Suture, White Braid	2, 38"	HC-5, 1N	12	OEM: Biomet	Feb-05	13907

Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

Name and Title of Approver:	Christine Ehmann Regulatory Affairs Manager, OEM
Signature of Approver:	
Date Approved:	27 MAR 2019
Site Where Approved:	Teleflex Medical OEM 375 Forbes Blvd Mansfield MA 02048

Canadian Classification

The following devices meet Canadian requirements as listed:

Device	Canadian License #	Issue Date	Class of Product
Force Fiber Surgical Sutures	83383	July 15, 2010	III
Force Fiber Surgical Sutures	83384	July 15, 2010	III

Product Description	Force Fiber White Braided Polyethylene Surgical Suture is a non-absorbable, sterile surgical suture composed of undyed (white) ultra high molecular weight polyethylene. Force Fiber White/Blue Co-braid is a non-absorbable, sterile surgical suture composed of undyed (white) ultra high molecular weight polyethylene braided with one or two strands of blue polypropylene to add color. The blue colorant is

[phthalocyaninato(2-)] copper with a concentration not to exceed 0.5% by weight.
Force Fiber White/Black Co-braid is a non-absorbable, sterile surgical suture composed of undyed (white) ultra high molecular weight polyethylene braided with one strand of black polyamide to add color. The black colorant is a logwood extract (hematein dye) with a concentration not to exceed 1.0% by weight.
Force Fiber Blue Braided Polyethylene Surgical Suture is a non-absorbable, sterile surgical suture composed of dyed (blue) ultra high molecular weight polyethylene. The blue-green pigment is chromium-cobalt-aluminum oxide with a concentration not to exceed 2.0% by weight.
Force Fiber White/Green Co-braid is a non-absorbable, sterile surgical suture composed of undyed (white) ultra high molecular weight polyethylene and green poly(ethylene terephthalate). The green colorant is D&C Green # 6 with a concentration not to exceed 0.75% by weight. It should be noted that Force Fiber® Green Co-braid may appear blue in color under certain lighting conditions.
Force Fiber sutures exceed USP specifications for diameter.

Suture Size	USP Ave. Diameter Specification (mm) <861>	Maximum Oversize Average Diameter (mm)	Maximum Oversize Average Diameter
5-0	0.100 - 0.149	0.149	0
4-0	0.150 - 0.199	0.224	0.025
3-0	0.200 - 0.249	0.318	0.069
2-0	0.300 - 0.339	0.363	0.024
0	0.350 - 0.399	0.406	0.007
1	0.400 - 0.499	0.541	0.042
2	0.500 - 0.599	0.630	0.031
3&4	0.600 - 0.699	0.754	0.055
5	0.700 - 0.799	0.861	0.062

Indications for Use

Force Fiber Polyethylene Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Intended Use

Force Fiber Polyethylene Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Contraindications

Force Fiber Surgical Sutures are contraindicated for cardiovascular use.

Manufacturing Site(s)

Manufacturing Site Name	Manufacturing Site Address
Teleflex Medical Mexico	Teleflex Medical de Mexico, S. de R.L. de C.V. Ave. Industrias No 5954 Parque Industrial Finsa, Nuevo Laredo, MEXICO 88275

Sterilizer

☐ N/A: The product is sold non-sterile.
☒ The product is sold sterile.

Sterilization Site Name	Sterilization Site Address
Sterigenics US, LLC	2971 Olympic Industrial Drive SE Suite 116 Atlanta, Georgia 30339 United States of America

Standards
The Legal Manufacturer claims compliance with the following standards:

Standard Number	Standard Name	Standard Issue Date
93/42/EEC MDD	Medical Device Directive as amended by 2007/47/EC	2007
EN ISO 13485	Medical Devices – Quality management systems – Requirements for regulatory purposes	2016
MDSAP (ISO 13485)	Medical Devices – Quality management systems – Requirements for regulatory purposes	2016
21CFR Part 820	Quality System Regulation	2018
CMDR	Canada Medical Device Regulations	2017
BS EN ISO 14971	Medical devices – Application of risk management to medical devices	2012
USP	United State Pharmacopeia <861>, <871>, <881>, Extractable Color as tested under Absorbable Suture	40
FDA Class II Special Controls Guidance	Surgical Sutures; Guidance for Industry and Staff	2003
BS EN ISO 14630	Non-active surgical implants – General requirements	2012
FDA Guidance	Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment	2014
ASTM F2052	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	2015
BS EN ISO 11607-1 +A1	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems	2010
ANSI/AAMI/ISO 11607-2	Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes	2006/(R)2010
ISTA P2A	Partial Simulation Performance Tests	2011
ASTM D4169	Standard Practice for Performing Testing of Shipping Containers	2014
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	2011
ASTM F88/F88M	Standard Test Method for Seal Strength of Flexible Barrier Materials	2009
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	2011
ISO 11135	Sterilization of healthcare products – Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices	2014
AAMI TIR 28	Product Adoption and Process Equivalency for Ethylene Oxide Sterilization	2016
AAMI TIR 15	Ethylene Oxide Sterilization Equipment, Process Considerations, And Pertinent Calculations	2016
ISO 11138-1	Sterilization of health care products – Biological indicators Part 1: General Requirements	2006
ISO 11138-2	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization process	2017
ISO 14161	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	2009(E)
ISO 14644-1	Cleanrooms and associated environments; classification of air cleanliness	2015

ISO 14644-2	Cleanrooms and associated environments; specification for testing and monitoring to prove continued compliance with ISO 14644-1	2015
BSI BS EN 556-1	Sterilization of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices	2001/Corrigendum No. 1:2006
ISO 10993-7	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	2008/Corrigendum No. 1:2006+C68
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2018
ISO 10993-3	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2003
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	2009
ISO 10993-6	Biological evaluation of medical devices Part 6: Tests for local effects after implantation	2016
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2010
ISO 10993-11	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	2017
ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012
BS EN ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements	2016
BS EN 1041 +A1	Information supplied by the manufacturer of medical devices AMD: October 31, 2013	2008
21 CFR Part 801	Labeling	2018
ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2013
NB-MED/2.7/Rec3	Evaluation of Clinical Data. Chapter 2.7 Clinical Investigations, Clinical Evaluation	1999
EU MEDDEV 2.7.1	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies	2016
EU MEDDEV 2.12-1	Guidelines on a Medical Devices Vigilance System	2013
EU MEDDEV 2.12-2	Guidelines on Post Market Clinical Follow-Up	2012