



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, INC.

Manufacturer's Address: Route 22 West
PO Box 151
Somerville, New Jersey 08876-0151
USA

Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Product: MERSILENE™ and MERSUTURE™ Braided and Monofilament
Synthetic Non-absorbable Sutures – Green Dyed and Undyed

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 13906

ADAPTIV No. 100103140

EC Class III Device Declaration
We, ETHICON INC, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.
This declaration is made on the basis of: EC Design Examination Certificate No. CE 01569, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC.
EC Quality System Certificate No. CE 00384, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 3.2 of Council Directive 93/42/EEC as amended by 2007/47/EC.

Place of Issue: Refer to Manufacture's Address above



Signature: _____ Date: June 9, 2020

Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

ATTACHMENT 1

Manufacturer's Name: ETHICON, INC.

Product: MERSILENE™ and MERSUTURE™ Braided and Monofilament Synthetic Non-Absorbable Sutures – Green Dyed and Undyed

MDD DD Number: 100103140

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 9.0 (Metric)
Suture Length	10 cm – 150 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Green
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Multifilament/Monofilament
Contains Antimicrobials (Yes/No)	No
Accessories to suture type	N/A
Needled/Non-Needled	Needled (Including CONTROL RELEASE Needles)/ Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, and ETHALLOY
Needle Coating	Silicone, MULTIPASS
Needle Shape	Straight/Curve
Needle Length	2 mm – 90 mm
Needle Wire Diameter	0.03 mm – 1.80 mm
Triclosan Maximum Levels (µg/m)	N/A