



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: 475C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico 00969
USA

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

Product: MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-absorbable Sutures

Product Range: See Attachment 1 for Product Range


Classification: Class III (Annex IX, Rule 8)

GMDN Code: 13910

MDD DD Number: 100193151

EC Class III Device Declaration
We, ETHICON, LLC, 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 555597, issued by 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 555605, issued by 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 Manufacturer's Address above

Signature:  Date: July 06, 2020

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

Signature:  Date: July 6, 2020

Title/Position: Carmen Gracia, Quality Systems Manager, Quality Operations

ATTACHMENT 1

Manufacturer's Name: ETHICON, LLC

Product: MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-absorbable Sutures

MDD DD Number: 100193151

SUTURE CODE RANGE – MERSILK™ AND PERMA-HAND™ BRAIDED SILK AND VIRGIN SILK STERILE NON-ABSORBABLE SUTURES (ETHICON, LLC GUAYNABO)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.2 – 7.0 (Metric)
Suture Length	20 cm – 180 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Blue
Coated/Uncoated	Coated / Uncoated
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Accessories to suture type	N/A
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Lengths	5 mm – 90 mm
Needle Wire Diameter	0.15 mm – 1.27 mm
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles) / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed