



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: Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile
Synthetic Absorbable Suture

Product Code(s)/Product Range and Description: Please refer to Attachment 1

Classification: Class III (Annex IX, Rule 8 and Rule 13)

GMDN Code: 45401

MDD DD Number: 100119364

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 591497, 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 Manufacturer's Address Above

Signature: 

September 24, 2020

Date: _____

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

ATTACHMENT 1

Manufacturer's Name: Ethicon, Inc.

Product: Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture

MDD DD Number: 100119364

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	1.0 –5.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Suture Coated / Uncoated (Coating material)	Coated (Copolymer of glycolide and lactide, calcium stearate)
Multifilament / Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels (µg/m)	≤ 275 µg/m
Accessories to suture type	N/A
Suture Needled / Non-Needled	Needled (including CONTROL RELEASE)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	10 mm – 80 mm
Needle Wire Diameter	0.305 mm – 1.550 mm