



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
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Product: VICRYL™ (Polyglactin 910) Sterile Synthetic
Absorbable Surgical Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)


GMDN Code: 17471

MDD DD Number: 100096038

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 555604, issued by the BSI Notified Body Number 2729, 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 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:  Date: 25-Feb-2019
Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

Signature:  Date: 26-Feb-2019
Title/Position: Carmen Gracia, Sr. Quality Systems Manager

ATTACHMENT 1

Manufacturer's Name: ETHICON, LLC Guaynabo
Product: VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture
MDD DD Number: 100096038

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.2 – 7.0 (metric)
Suture Length	5 cm – 250 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and L-lactide, calcium stearate) /Uncoated
Multifilament/Monofilament	Multifilament / Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Needled (also available with 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, CERBERUS, MULTIPASS
Needle Shape	Curve / Straight
Needle Color	Silver / Black
Needle Length	2 mm - 110 mm
Needle Wire Diameter	0.015 mm – 1.80 mm

Manufacturer's Name: ETHICON, LLC Guaynabo
 Product: Endosuture System made with VICRYL™ Suture
 MDD DD Number: 100096038

Endosuture System (ESS) ENDOLOOP™ Characteristics	Range
Suture Gauge Size	3.5 (Metric)
Suture Length	50 (cm)
Suture Dyed/Undyed	Dyed
ESS passer/slider material	High-Density Polyethylene, Black

Endosuture System (ESS) ENDONEEDLE™ Characteristics	Range
Suture Gauge Size	1.5, 2, 3, 3.5 (Metric)
Suture Length	110 (cm)
Suture Dyed/Undyed	Dyed
Needle Material	ETHALLOY
Needle Coating	Silicone
Needle Shape	Curved
Needle Length	20, 23.8, 24 (mm)
ESS passer/slider material	High-Density Polyethylene, Black

Manufacturer's Name: ETHICON, LLC Guaynabo

Product: VICRYL™ Suture Cartridge for PROXISURE™

MDD DD Number: 100096038

VICRYL™ Suture Cartridge for PROXISURE™ Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	2 – 3.5 (Metric)
Suture Length	122 cm
Suture Dyed/Undyed	Dyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and lactide, calcium stearate)
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Needled
Number of Needles per Suture	Single Armed
Needle Material	420 SS
Needle Coating	Silicone
Needle Shape	Curve
Needle Length	21 mm
Needle Wire Diameter	0.74 mm