

**ETHICON** LLC

a *Johnson & Johnson* company

## DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: 475 C 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: VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 17471

MDD DD Number: 100159452

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 574854, 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 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: July 07, 2020

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

Place of Issue: Refer to Manufacturer's Address above

Signature:  Date: July 07, 2020

Title/Position: Carmen Gracia, Senior Quality Systems Manager

## ATTACHMENT 1

Manufacturer's Name: ETHICON, LLC

Product: VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture

MDD DD Number: 100159452

### SUTURE CODE RANGE – VICRYL RAPIDE (ETHICON, LLC – GUAYNABO)

<b>Suture Characteristics</b>	<b>Range</b>
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	30 cm – 150 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated
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 / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, 4310 FB SS and ETHALLOY
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	5.5 mm – 60 mm
Needle Wire Diameter	0.15 mm – 1.27 mm