

## Johnson & Johnson International

LEONARDO DA VINCI LAAN 15  
BE-1831 DIEGEM • BELGIË

### DECLARATION OF CONFORMITY

Manufacturer's Name: Johnson & Johnson International

Manufacturer's Address: c/o European Logistics Centre  
Leonardo Da Vincilaan 15  
BE-1831 Diegem  
Belgium

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, Johnson & Johnson International, 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 00585, issued by the BSI 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 589698, 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: Debbie Fazen Date: May 10, 2021

Title/Position: Debbie Fazen, Associate Director, Regulatory Affairs

Signature: [Signature] Date: May 21, 2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

## ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International  
Product: VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture  
MDD DD Number: 100096038

<b>Suture Characteristics</b>	<b>Range</b>
Surgical Suture Material (Absorbable/Non-Absorbable)	Absorbable
Surgical Suture Gauge Size	0.2 – 8.0 (Metric)
Surgical Suture Length	5 cm – 2.5 m
Surgical Suture Dyed/Undyed	Dyed / Undyed
Surgical 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	3.5 mm – 110 mm
Needle Wire Diameter	0.015 mm – 1.60 mm