



LEONARDO DA VINCILAAN 15
BE-1831 DIEGEM - Belgium

DECLARATION OF CONFORMITY

Manufacturer's Name: Johnson & Johnson International

Manufacturer's Address: Johnson & Johnson International
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 is made on the basis of: EC Design Examination Certificate No. CE 00585, issued by the BSI Notified Body Number 0086, 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 Notified Body Number 0086, 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: October 5, 2017

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

Signature:  Date: October 6, 2017

Title/Position: Amparo Martos, JJI/ELC QA Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
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 – 8.0 (Metric)
Suture Length	5 cm – 2.5 m
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	3.5 mm – 110 mm
Needle Wire Diameter	0.015 mm – 1.60 mm