



LEONARDO DA VINCILAAN 15
BE-1831 DIEGEM - Belgium

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

Authorized Representative: N/A

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, 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 73804, 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 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 25, 2021

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

Signature: [Signature] Date: MAY 26, 2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
 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	5 cm – 250 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Coated / Uncoated	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
Needled / Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420, 420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver/Black
Needle Length	3.5 mm – 110 mm
Needle Wire Diameter	0.10 mm – 1.55 mm