




LEONARDO DA VINCI LA 116
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
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, 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 00584, 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:  _____ **Date:** July 07, 2020

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

Signature:  _____ **Date:** JULY 07, 2020

Title/Position: Veronica Ysunza, Manager, Quality Assurance

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture
MDD DD Number: 100159452

SUTURE CODE RANGE – VICRYL RAPIDE (JOHNSON & JOHNSON INTERNATIONAL)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	45 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