



LEONARDO DA VINCILAAAN 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
Authorized Representative:	N/A
Product:	Coated VICRYL™ Plus Antibacterial 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:	ADAPTIV No.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 is made on the basis of:

EC Design Examination Certificate No. CE 73804, issued by the British Standards Institute 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 British Standards Institute 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: August 30, 2016

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

Signature:  Date: August 30, 2016

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: Coated VICRYL™ Plus Antibacterial 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
Suture 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
Suture 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 Length	3.5 mm – 110 mm
Needle Wire Diameter	0.10 mm – 1.55 mm