

Johnson & Johnson International

LEONARDO DA VINCI LAAN 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

Product: PDS™ Plus Antibacterial (polydioxanone) Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8 and Rule 13)

GMDN Code: 47362

MDD DD Number: 100193159

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 536533, 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: 5/21/2021

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

Signature: [Signature] Date: 5/25/2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: PDS™ Plus Antibacterial (polydioxanone) Suture
MDD DD Number: 100193159

Suture Characteristic	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	35 cm - 245 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Suture Coated/Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels	≤ 2360 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 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Colour	Silver / Black
Needle Length	7.9 mm - 70 mm
Needle Wire Diameter	0.20 mm – 1.55 mm