



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: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic
Non-absorbable Surgical Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 13909

MDD DD Number: 100159465

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 00480, 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: March 7, 2019

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

Signature:  Date: MARCH 07, 2019

Title/Position: Veronica Ysunza , Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
 Product: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic
 Non-absorbable Surgical Suture

MDD DD Number: 100159465

SUTURE CODE RANGE – PROLENE™ SUTURE (JOHNSON & JOHNSON INTERNATIONAL)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	45 cm – 90 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Blue
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Tubing, Ethisorb Pledgets
Needled/Non-Needled	Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle material	420 SS, 455 SS, 4310 SS, and ETHALLOY
Needle coating	CERBERUS, Silicone, MULTIPASS + Additional Coating of Silicone (Double Dip)
Needle Shape	Curve
Needle Color	Silver/Black
Needle Length	6.5 mm – 90 mm
Needle Wire Diameter	0.152 mm – 1.27 mm

Manufacturer's Name: Johnson & Johnson International
Product: ENDOLOOP™ made with PROLENE™ Suture (also referred to as ETHIBINDER)
MDD DD Number: 100159465

CODE RANGE – ENDOLOOP MADE WITH PROLENE™ SUTURE (JOHNSON & JOHNSON INTERNATIONAL)

ENDOLOOP™ Characteristics	Range
Suture Gauge Size	3 (Metric)
Suture Length	90 cm
Suture Dyed/Undyed	Dyed (Blue)
Cannula specifications	Material: Nylon 11 Length: 38 cm OD: 3.9 mm