



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

Product: MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile
Synthetic Absorbable Surgical Suture

Product Range and Description: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

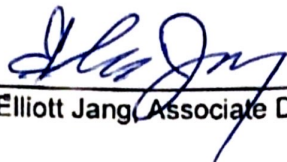
GMDN Code: 16584

MDD DD Number: ADAPTIV No. 100119315

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 01305, 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 1, 2020
Elliott Jang, Associate Director, Regulatory Affairs

Title/Position:

Signature:

 Date: July 01, 2020

Title/Position:

Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International

Product: MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile
Synthetic Absorbable Surgical Suture

MDD DD Number: ADAPTIV No. 100119315

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 cm – 250 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Non-Needled / Needled (also available with CONTROL RELEASE™ needles)
Number of Needles per Suture	Single Armed / Double Armed
Needle material	420 SS, 4310 SS and ETHALLOY
Needle coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Black / Silver
Needle Length	8 mm - 70 mm
Needle Wire Diameter	0.25 mm – 1.45 mm