



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: ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic Non-Absorbable Surgical Suture

Product Range: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 38000

MDD DD Number: 100173897

EC Class III Device Declaration
We, Johnson and 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: Design Certificate No. CE 01326, 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.
Full Quality Assurance 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:** 07 May 2020
Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

Signature:  **Date:** 07, May 2020
Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic Non-Absorbable Surgical Suture
MDD DD Number: 100173897

SUTURE CODE RANGE – ETHILON SUTURE (JOHNSON & JOHNSON INTERNATIONAL)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.2 – 5.0 Metric
Suture Length	45 cm - 250 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Black
Coated / Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes / No)	No
Triclosan Levels (µg/m)	N/A
Accessories to suture type	Retention Tubing
Needled / Non-Needled	Needled / Non-Needled
Number of Needles per Suture	Single Armed/ Double Armed
Needle Material	420 SS, 4310 SS
Needle Coating	Silicone, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Sliver/Black
Needle Length	8mm – 75mm
Needle Wire Diameter	0.20 mm – 1.02 mm