



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

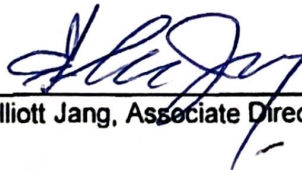
We, Johnson and Johnson International, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.

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



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: Highway 183 Km 8.3
San Lorenzo 00754
Puerto Rico
USA

Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

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

Product Range Classification: See Attachment 1
Class III (Annex IX, Rule 8)

GMDN Code: 38000

MDD DD Number: ADAPTIV No. 100173897

EC Class III Device Declaration
We, ETHICON LLC, 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 549317, 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 549314, 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: May 24, 2021

Title/Position: Debbie Fazen, Associate Director Regulatory Affairs

Signature: Adnyl Grovas Date: 17 JUN 2021

Title/Position: Adnyl Grovas, Director, Plant Quality Assurance

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC San Lorenzo
 Product: ETHILON™ (Polyamide 6 or 6,6) Sterile Synthetic
 Non-Absorbable Surgical Suture
 MDD DD Number: 100173897

SUTURE CODE RANGE – ETHILON SUTURE (SAN LORENZO)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 5.0 (Metric)
Suture Length	5 cm - 200 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Green
Suture Coated / Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/ No)	No
Triclosan Levels (µg/m)	N/A
Accessories to suture type Needed / Non-Needed	Lead Seal and Surgical Bolster, Retention Tubing Needed / Non-Needed
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, 455 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm