



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

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

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

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, 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 549330, 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 this Directive 93/42/EEC as amended by 2007/47/EC.

Place of Issue: Refer to Manufacturer's Address Above

Signature: Debbie Fazen Date: May 10, 2021

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

Signature: Adnyl Grovas Date: May 22, 2021

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

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC
 Product: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-Absorbable Surgical Suture

MDD DD Number: 100159465

SUTURE CODE RANGE – PROLENE™ (ETHICON, LLC SAN LORENZO)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.2 – 5.0 (Metric)
Suture Length	7 cm – 150 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	Ethilock Fixation Clips (Ethilock locking buttons), PTFE Pledgets
Additional presentations	HEMO-SEAL needle suture combination
Needled/Non-Needled	Needled (also available with CONTROL RELEASE needles)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY and Tungsten/Rhenium
Needle Coating	Silicone, EVERPOINT, CEREBUS, MULTIPASS, MULTIPASS + Additional Coating of Silicone (Double-Dip)
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Dimensions (Except EVERPOINT™)	
Needle length	3.8 mm – 90 mm
Needle wire diameter	0.076 mm – 1.448 mm
Needle Dimensions (EVERPOINT™)	
Needle length	6.5 mm – 13 mm
Needle wire diameter	0.1524 mm – 0.2667 mm




DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, INC.
Manufacturer's Address: Route 22 West
PO Box 151
Somerville, New Jersey 08876-0151
USA
Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany
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, ETHICON, INC, 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 00871, issued by the BSI Group The Netherlands Group 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 00384, issued by the BSI Group The Netherlands Group 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: 11-MAY-2020

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

ATTACHMENT 1

Manufacturer's Name: Ethicon, Inc.
 Product: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic
 Non-absorbable Surgical Suture
 MDD DD Number: 100159465

SUTURE CODE RANGE – PROLENE™ SUTURE (ETHICON, INC.)

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.2 – 5.0 (Metric)
Suture Length	7 cm – 150 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	Beads and Collars, Ethilock Fixation Clips, PTFE Pledgets
Additional Presentation	HEMO-SEAL needle suture combination
Needled/Non-Needled	Needled (also available with CONTROL RELEASE needles)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, 4310FB SS, ETHALLOY and Tungsten/Rhenium
Needle Coating	Silicone, MULTIPASS, EVERPOINT, CERBERUS, MULTIPASS + Additional Coating of Silicone (Double-Dip)
Needle Shape	Straight/Curve
Needle Color	Black / Silver
Needle Dimensions (Except EVERPOINT™)	
Needle length	3.8 mm – 90 mm
Needle wire diameter	0.076 mm – 1.448 mm
Needle Dimensions (EVERPOINT™)	
Needle length	6.5 mm – 13 mm
Needle wire diameter	0.1524 mm – 0.2667 mm

Manufacturer's Name: Ethicon, Inc.
Product: Endosuture System made with PROLENE™ Suture
MDD DD Number: 100159465

CODE RANGE – ENDOSUTURE SYSTEM MADE WITH PROLENE™ SUTURE (ETHICON, INC.)

Endosuture System (ESS) ENDONEEDLE™ Characteristics	Range
Suture Gauge Size	3 (Metric)
Suture Length	110 cm
Suture Dyed/Undyed	Dyed (Blue)
Needle Material	ETHALLOY
Needle Coating	Silicone
Needle Shape	Curve
Needle Length	24 mm
ESS passer/slider material	High-Density Polyethylene, Black



LEONARDO DA VINCILAAAN 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: 12 May 2020

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

Signature:  Date: 12 May 2020

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