



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, INC.

Manufacturer's Address: 1000 Route 202
Raritan
New Jersey
08869
USA

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

Product: PDS™ II (Polydioxanone) Sterile Synthetic, Absorbable Suture
Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 16584

MDD DD Number: 100142376

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 00874, 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 00384, 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: May 25, 2021

Title/Position:

Debbie Fazen, Associate Director, Regulatory Affairs

ATTACHMENT 1

Manufacturer's Name: ETHICON, INC.
Product: PDS™ II (Polydioxanone) Sterile Synthetic, Absorbable
Suture
MDD DD Number: 100142376

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.5 – 5.0 (Metric)
Suture Length	20 cm – 240 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	Needled / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Length	6.5 mm – 254 mm
Needle Wire Diameter	0.152 mm – 1.45 mm

Manufacturer's Name: ETHICON, INC.
Product: ENDOKNOT™ made with PDS™ II Suture
MDD DD Number: 100142376

ENDOKNOT™ Characteristics	Range
Suture Gauge Size	3, 3.5, 4 (Metric)
Suture Length	100, 107, 120 (cm)
Suture Dyed/Undyed	Dyed
Needle Material	420 SS, 4310 SS
Needle Coating	Silicone
Needle Shape	Straight / Curve
Needle Length	19, 22, 26, 30 mm
Cannula Specifications	Material: Nylon 11, Nylon 12 Length: 30.5 cm, 38 cm OD: 3.9 mm

Manufacturer's Name: ETHICON, INC.
Product: ENDOLOOP™ made with PDS™ II Suture
MDD DD Number: 100142376

ENDOLOOP™ Characteristics	Range
Suture Gauge Size	2, 3, 3.5, 4 (Metric)
Suture Length	45, 53, 63 (cm)
Suture Dyed/Undyed	Dyed
Cannula Specifications	Material: Nylon 11, Nylon 12 Length: 30.5 cm, 38 cm OD: 3.9 mm