



### DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, INC.  
Manufacturer's Address: Route 22 West  
PO Box 151  
Somerville, New Jersey 08876-0151  
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:

June 26, 2020

Date: \_\_\_\_\_

Title/Position:

Elliott Jang, Associate Director, Regulatory Affairs

## ATTACHMENT 1

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

<b>Suture Characteristics</b>	<b>Range</b>
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

<b>ENDOKNOT™ Characteristics</b>	<b>Range</b>
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

<b>ENDOLOOP™ Characteristics</b>	<b>Range</b>
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

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

<b>Endosuture System (ESS) ENDOLOOP™ Characteristics</b>	<b>Range</b>
Suture Gauge Size	3.5 (Metric)
Suture Length	50 cm
Suture Dyed/Undyed	Dyed
ESS passer/slider material	High-Density Polyethylene, Black

<b>Endosuture System (ESS) ENDONEEDLE™ Characteristics</b>	<b>Range</b>
Suture Gauge Size	3 (Metric)
Suture Length	110 (cm)
Suture Dyed/Undyed	Dyed
Needle Material	ETHALLOY, 4310 SS
Needle Coating	Silicone
Needle Shape	Curve
Needle Length	24, 26 (mm)
ESS passer/slider material	High-Density Polyethylene, Black