



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: 475C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico 00969
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 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 555601, 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 555605, 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: June 29, 2020
Title/Position: Elliott Jang, Associate Director, Regulatory Affairs

Signature:  Date: June 29, 2020
Title/Position: Carmen Gracia, Senior Quality Systems Manager

ATTACHMENT 1

Manufacturer's Name: ETHICON, LLC
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 Color	Silver / Black
Needle Length	6.5 mm – 254 mm
Needle Wire Diameter	0.152 mm – 1.45 mm

Manufacturer's Name: ETHICON, LLC

Product: Endosuture System made with PDS™ II Suture

MDD DD Number: 100142376

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

Endosuture System (ESS) ENDONEEDLE™ Characteristics	Range
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