



## 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)

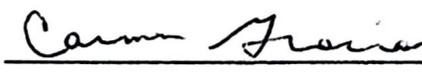
GMDN Code: 16584

MDD DD Number: 100142376

<b>EC Class III Device Declaration</b>
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

<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 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

<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

## SUPPLEMENTARY INFORMATION

### Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100163693 | Rev: 18  
DoC for PDS™ II Suture – Non-significant changes approved after the 26<sup>th</sup> May 2021 as  
per Transitional Provisions of MDR Article 120.3

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The transitional provisions specified in MDR Article 120(3) prohibit manufacturers from issuing new Declaration of Conformities or amending, modifying, supplementing any existing MDD Declaration of Conformity from 26<sup>th</sup> May 2021.

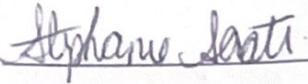
This letter is to confirm that Ethicon Wound Closure and Healing has reviewed and approved the change(s) detailed in the table below. These changes do not represent a change in design or intended purpose under MDR Article 120(3). Declaration of Conformity 100163693 | Rev: 18 DoC for PDS™ II Suture remains valid.

#### Changes Approved:

Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
See Signature	101014129	CE 555601	3477754	Adding header to the DoC  Updated Section A.4 for Ethicon, LLC.: Review of Janssen Pharmaceutical, Athens GA as an additional raw material manufacturer and supplier of P-Dioxanone monomer.
14-Jun-2022	100953227	CE 555601	3513638	Review of DoC initiated as DEC is renewed –no impact to DoC

				Updated Section A.4 for Ethicon, LLC.: Adding Conversion of the SS2 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization of absorbable products utilizing the X Cycle.
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Place of Issue: Refer to Manufacturer's Address above

Signature:  Date: 07-NOV-2022  
(wet sign only)

Title/Position: Stephanie Saati, Associate Director, Regulatory Affairs

Signature:  Date: 08-NOV-2022  
(wet sign only)

Title/Position: Marjorie Medina, SR DIRECTOR Supply Chain Quality EES BIO