



## 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:

A handwritten signature in black ink, appearing to read "Debbie Fazen", is written over a horizontal line.

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

## SUPPLEMENTARY INFORMATION

### Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100163692 | 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

Manufacturer's Name: ETHICON, INC.  
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USA

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 100163692 | 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 00874	3477679	Update per template FM-0001846 – no impact to DoC  Updated Section A.4 for Ethicon, Inc. Addition of the Janssen Pharmaceutical, Athens GA site as a raw material supplier of P-Dioxanone monomer used in the



				manufacture of PDS II Suture by Ethicon, Inc.
14-Jun- 2022	100953227	CE 555601	3513637	Review of DoC initiated as DEC is renewed –no impact to DoC

Place of Issue: Refer to Manufacturer's Address above

Signature:  
(wet sign only)

*Stephanie Saati*

Date: 04-Nov-2022

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

Signature:  
(wet sign only)

*Linda Plews*

Date: 14-Nov-2022

Title/Position: Linda Plews, Director Quality Sys and Digital Soln