ETHICON LLC
a Johnson & Johnson company

DECLARATION OF CONFORMITY

Manufacturer's Name:	ETHICON LLC
Manufacturer's Address:	475 C Street Los Frailes Industrial Park Suite 401 Guaynabo Puerto Rico 00969 USA
Authorized Representative:	Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany
Product:	STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device and STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device
Product Ranges and Descriptions:	See Attachment 1 for Product Range and Descriptions
Classification:	Class III (Annex IX, Rule 8 & 13)
GMDN Code:	64234
MDD DD Number:	100306967

Regulatory Affairs Submission
Declaration of Conformity
DoC for STRATAFIX PDS Plus Knotless Tissue Control Device
Product Family

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 630873, 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, Date: Refer to Manufacturer's Address Above

Signature: _____ Date: May 05, 2020
Title/Position: Joice Pappan, Manager, Regulatory Affairs

Signature: _____ Date: April 27, 2020
Title/Position: Carmen Gracia, Sr. Quality Systems Manager

ATTACHMENT 1

Manufacturer's Name: ETHICON LLC

Product: STRATAFIX™ Symmetric PDS™ Plus Knotless Tissue Control Device

MDD DD Number: 100306967

STRATAFIX Symmetric PDS Plus Suture	
Suture Material (Absorbable / Non-Absorbable)	Absorbable
Barbing Orientation	Symmetric
Suture Gauge Size	2 – 4 Metric
Suture Length	15-60 cm
Suture Color	Violet
Suture Coated / Uncoated	Uncoated
Suture Needled / Non-Needled	Needled
Contains Antimicrobials (Yes / No)	Yes
Triclosan Maximum Levels (µg/m)	≤ 2360 µg/m
Needle Material	ETHALLOY, 420 SS
Needle Coating	Silicone, CERBERUS
Needle Shape	Straight / Curve
Needle Length	17 – 48 mm
Needle Wire Diameter	0.6604 – 1.27 mm

Manufacturer's Name: ETHICON LLC

Product: STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device

MDD: TF/DD Number: 100306967

STRATAFIX Spiral PDS Plus Suture	
Suture Material (Absorbable / Non-Absorbable)	Absorbable
Barbing Orientation	Spiral
Suture Gauge Size	1.5 – 4 Metric
Suture Length	15 – 90 cm
Suture Color	Violet
Suture Coated / Uncoated	Uncoated
Suture Needled / Non-Needled	Needled
Contains Antimicrobials (Yes / No)	Yes
Triclosan Maximum Levels (µg/m)	≤ 2360 µg/m
Needle Material	ETHALLOY, 420 SS, 4310 SS
Needle Coating	Silicone, CERBERUS and MULTIPASS
Needle Shape	Straight / Curve
Needle Length	16 – 48 mm
Needle Wire Diameter	0.5588-1.27 mm

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100275128 | Rev 12 DoC for STRATAFIX PDS Plus Knotless Tissue Control Device Product Family– Non-significant changes approved after the 26th May 2021 as per Transitional Provisions of MDR Article 120.3

Manufacturer's Name:	ETHICON LLC
Manufacturer's Address:	475 C Street Los Frailes Industrial Park Suite 401 Guaynabo Puerto Rico 00969 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 26th 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 100275128 | Rev 12 DoC for STRATAFIX PDS Plus Knotless Tissue Control Device Product Family 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	101010050	CE 630873	3477757	Review of DoC initiated as DEC is renewed –no impact to DoC
18-Jul-2022	100992980	N/A	N/A	Adding header to the DoC
15-Jun-2022	100950880	CE 630873	3281519	Review of DoC initiated as DEC is renewed –no impact to DoC

18-Aug-2021	100917351	CE 630873	3281519	Review of DoC initiated by update of Design Dossier –no impact to DoC

Place of Issue: Refer to Manufacturer's Address above

Signature:
(wet sign only)

Date: October 20, 2022

Title/Position: Joice Pappan, Regulatory Affairs Manager

Signature:
(wet sign only)

Date: Oct-20-2022

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