



## 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

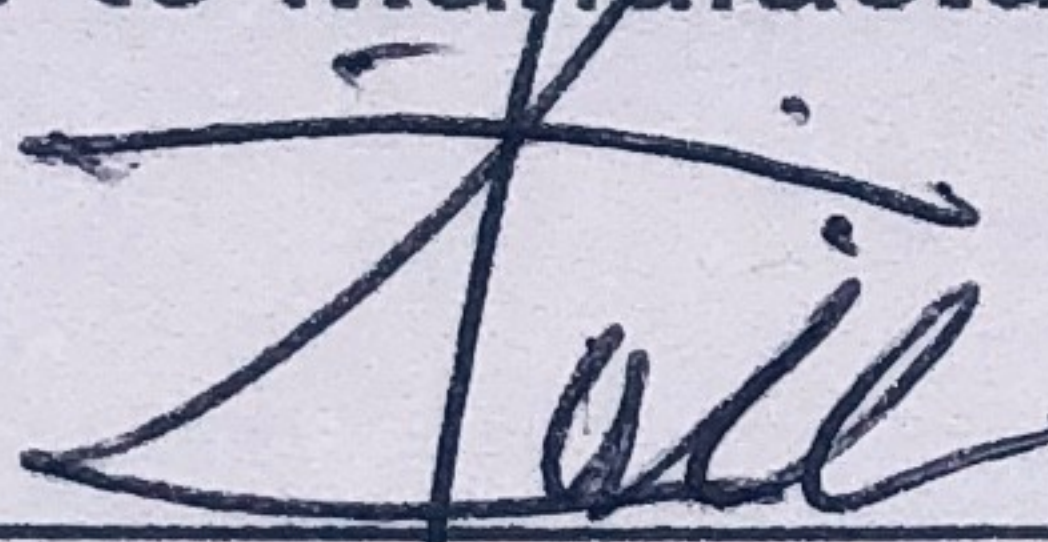
MDD DD Number: 100306967

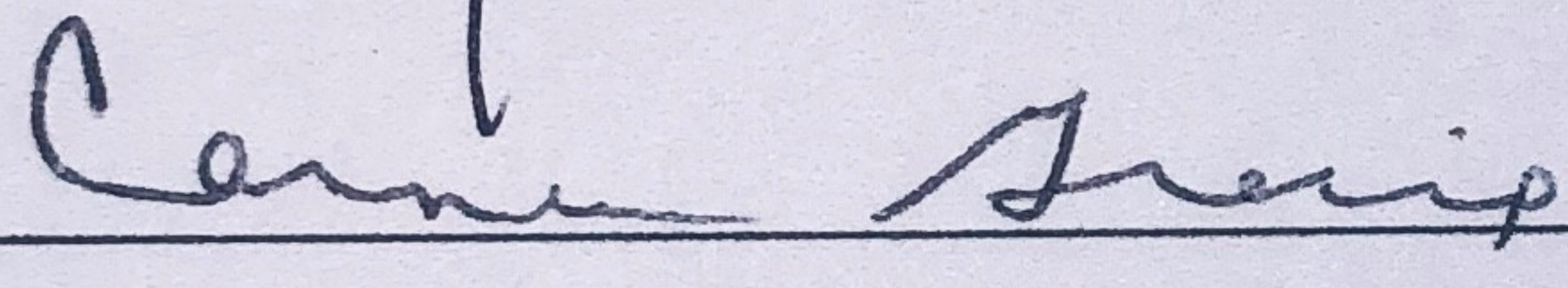


Regulatory Affairs Submission  
Declaration of Conformity  
DoC for STRATAFIX PDS Plus Knotless Tissue Control Device  
Product Family

|  |
|--|
| <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:<br>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

| <b>STRATAFIX Symmetric PDS Plus Suture</b>    |                    |
|---|--------------------|
| 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

| <b>STRATAFIX Spiral PDS Plus Suture</b>       |                                  |
|---|----------------------------------|
| 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 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 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