



DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Product: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-Absorbable Surgical Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 13909

MDD DD Number: 100159465

| 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 549330, 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 549314, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 3.2 of this Directive 93/42/EEC as amended by 2007/47/EC. | |

Place of Issue: Refer to Manufacturer's Address Above

Signature: Debbie Fazen Date: May 10, 2021

Title/Position: Debbie Fazen, Associate Director, Regulatory Affairs

Signature: Adnyl Grovas Date: May 22, 2021

Title/Position: Adnyl Grovas, Director, Plant Quality Assurance

ATTACHMENT 1

Manufacturer's Name: Ethicon, LLC
Product: PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-Absorbable Surgical Suture

MDD DD Number: 100159465

SUTURE CODE RANGE – PROLENE™ (ETHICON, LLC SAN LORENZO)

| Suture Characteristics | Range |
|--|--|
| Suture Material (Absorbable/Non-Absorbable) | Non-Absorbable |
| Suture Gauge Size | 0.2 – 5.0 (Metric) |
| Suture Length | 7 cm – 150 cm |
| Suture Dyed/Undyed | Dyed/Undyed |
| Suture Color (If dyed) | Blue |
| Coated/Uncoated | Uncoated |
| Multifilament/Monofilament | Monofilament |
| Contains Antimicrobials (Yes/No) | No |
| Triclosan Maximum Levels (µg/m) | N/A |
| Accessories to suture type | Ethilock Fixation Clips (Ethilock locking buttons), PTFE Pledgets |
| Additional presentations | HEMO-SEAL needle suture combination |
| Needled/Non-Needled | Needled (also available with CONTROL RELEASE needles) |
| Number of Needles per Suture | Single Armed/Double Armed |
| Needle Material | 420 SS, 455 SS, 4310 SS, ETHALLOY and Tungsten/Rhenium |
| Needle Coating | Silicone, EVERPOINT, CEREBUS, MULTIPASS, MULTIPASS + Additional Coating of Silicone (Double-Dip) |
| Needle Shape | Straight/Curve |
| Needle Color | Silver/Black |
| Needle Dimensions (Except EVERPOINT™) | |
| Needle length | 3.8 mm – 90 mm |
| Needle wire diameter | 0.076 mm – 1.448 mm |
| Needle Dimensions (EVERPOINT™) | |
| Needle length | 6.5 mm – 13 mm |
| Needle wire diameter | 0.1524 mm – 0.2667 mm |

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100200612 | Rev: 19
DoC for PROLENE Suture Product Family – Non-significant changes approved after the
26th 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 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 100200612 | Rev: 19 DoC for PROLENE Suture 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 | 100985524 | N/A | N/A | GMDN term is uptaded from <i>Polypropylene Suture</i> to <i>Polyolefin Suture, monofilament</i> . |

Place of Issue: Refer to Manufacturer's Address above

Signature:  Date: 13 Dec 2022
(wet sign only)

Title/Position: Valerie Smith-Beyer, Director, Regulatory Affairs

Signature:  Date: 13 / Dec. / 2022
(wet sign only)

Title/Position: Jenniffer Ruiz Tubens, Site QA Lead