# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 00874**

Issued To: **Ethicon, Inc.**
**1000 Route 202**
**Raritan**
**New Jersey**
**08869**
**USA**

In respect of:

**PDS™ II (Polydioxanone) Sterile Synthetic, Absorbable Suture**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1995-10-02** Date: **2021-05-21** Expiry Date: **2024-05-26**

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**PDS™ II (Polydioxanone) Sterile Synthetic Absorbable Surgical Suture Needle and Suture combinations from within the following limits are Class III devices, intended for use in general soft tissue approximation, including use in pediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.**

| **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 Colour (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 |

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| **Suture Characteristics** | **Range** |
|---|---|
| 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 |

| **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<br>Length: 30.5 cm, 38 cm<br>OD: 3.9 mm |

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| **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<br>Length: 30.5 cm, 38 cm<br>OD: 3.9 mm |

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# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 02 October 1995 | MD000016 | First issue. |
| 02 October 2000 | 10019295 | USP size, suture and needle lengths and needle diameters added on appendix page.<br>Certificate renewal. |
| 27 April 2005 | 10068165 | San Angelo primary ETO Sterilization cycle 'B' approved. |
| 23 May 2005 | 10067315 | San Angelo primary ETO Sterilization cycle 'L' approved. |
| 21 September 2005 | 10072882 | Certificate renewal. |
| 11 July 2007 | 10089038 | Add J&J Brazil as a needle attachment, packaging and sterilization site. |
| 27 February 2008 | 10093247 | Change sterilization process from cycle "B" to cycle "X". |
| 19 December 2008 | 10100735 | Change of product release method from Biological Indicators to Parametric Release. |

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| Date | Reference Number | Action |
|---|---|---|
| 12 October 2010 | 10117944 | Certificate renewal. |
| 05 November 2014 | 10151485 | Administrative update to certificate format.<br>Administrative update to supplementary page table.<br>Certificate renewal. |
| 22 June 2015 | 10151488 | Administrative update to supplementary page information.<br>Review of updated labels and IFU. |
| 23 September 2015 | 10154124 | Increase needle range to 8mm - 254mm. |
| 04 December 2015 | 10153616 | Addition of CERBERUS needle coating type and CERBERUS coating process at Norderstedt, Germany.<br>Addition of Needle Master File. |
| 18 March 2016 | 10159048 | Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). |
| 03 August 2016 | 10162190 | Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.<br>Administrative update to supplemental information. |
| 12 January 2017 | 10153298 | Addition of ENDOKNOT, ENDOLOOP, Endosuture System ENDOLOOP, and Endosuture System ENDONEEDLE. |

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| Date | Reference Number | Action |
|---|---|---|
| 07 February 2017 | 10167383 | Addition of CERBERUS coating process at Ethicon Cornelia, Georgia. |
| 13 March 2017 | 10162842 | Addition of site capacity to increase suture manufacturing flexibility.<br>Suture gauge size, needle length and needle wire diameter ranges extended. |
| 11 August 2017 | 8716374 | Review of BC5 blanking and cartoning machine at San Angelo, TX site. |
| 23 October 2017 | 8678797 | Addition of manufacturing capacity for a subset of product codes at Ethicon Inc., Juarez, Mexico; extension of needle wire diameter range; addition of MULTIPASS needle coating.<br>Extension of the needle wire diameter range to 0.152 mm. |
| 19 June 2018 | 8935272 | Addition of Athens, GA Suture Raw Material Manufacturing Facility for sizes Metric 1.5 ,(USP 4-0) Metric 2 (3-0), and Metric 3 (USP 2-0). |
| 1 February 2019 | 8748332 | Review of PDO monomer supplier change. |
| 22 February 2019 | 7781191 | Traceable to NB 0086. |

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| Date | Reference Number | Action |
|---|---|---|
| 05 September 2019 | 9665148 | Retrofit of sterilization equipment on the SS1 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization utilizing the X Cycle.<br>Administrative update to the supplementary page to include classification and intended purpose. |
| 20 September 2019 | 9714724 | Certificate renewal.<br>Inclusion of additional suture gauge sizes. |
| 29 January 2020 | 9690310 | Addition of Multi-slide-based needle manufacturing process for ETHALLOY laser drilled needles at Johnson & Johnson Medical GmbH (Norderstedt, Germany) and Johnson & Johnson do Brasil (São José dos Campos, Brazil) manufacturing facilities.<br>Addition of wire drawing for ETHALLOY stainless steel, 420 SS and 455 SS Johnson & Johnson Medical GmbH (Norderstedt, Germany) and Johnson & Johnson do Brasil (São José dos Campos, Brazil) manufacturing facilities. |
| 02 June 2020 | 9688896 | Manual stake swage change at the Ethicon, Inc. (Juarez) manufacturing facility. |

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| Date | Reference Number | Action |
|---|---|---|
| Current | 3201650 | Change of Legal Manufacturer address to 1000 Route 202, Raritan, New Jersey, 08869, USA.<br>Removal of the following suture configurations from scope of CE 00874: Endosuture System (EES) ENDOLOOP made with PDS II Suture and Endosuture System (ESS) ENDONEEDLE made with PDS II Suture. |

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By Royal Charter

**Supplementary Information to CE 00874 -** Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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**Date:** 30 June 2022

**Changes Approved:**

| Date | Reference Number | Action |
|---|---|---|
| 30 June 2022 | 3477679 | Review of Janssen Pharmaceutical, Athens GA as an additional raw material manufacturer and supplier of P-Dioxanone monomer. |

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30 June 2022

Ethicon, Inc.
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

| **Certificate** | **Directive and Annex** | **Reference Number** | **Changes approved** |
|---|---|---|---|
| CE 00874 | 93/42/EEC Annex II Section 4 | 3477679 | 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. |

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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