

# 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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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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 Length: 30.5 cm, 38 cm 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 Length: 30.5 cm, 38 cm 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. 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. Administrative update to supplementary page table. Certificate renewal.
22 June 2015	10151488	Administrative update to supplementary page information. 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. 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. 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. 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. 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. Administrative update to the supplementary page to include classification and intended purpose.
20 September 2019	9714724	Certificate renewal. 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. 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	<p>Change of Legal Manufacturer address to 1000 Route 202, Raritan, New Jersey, 08869, USA.</p> <p>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.</p>

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**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.

30 June 2022

Ethicon, Inc.  
1000 Route 202  
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To whom it may concern,

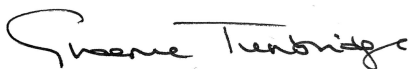
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

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