EC Design-Examination Certificate

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

No. **CE 536533**

Issued To: **Johnson & Johnson International**
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

In respect of:

PDS™ Plus Antibacterial (polydioxanone) 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: **2009-04-03** Date: **2021-04-05** Expiry Date: **2024-05-26**

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Product: PDS™ Plus Antibacterial (polydioxanone) Suture in the following limits are Class III devices, intended for use in general soft tissue approximation, including use in pediatric cardiovascular tissue.

SUTURE CHARACTERISTICS	RANGE
Suture Material (Absorbable / Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	35 cm - 245 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet
Suture Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels	≤ 2360 µg/m
Accessories to suture type	N/A
Suture 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, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight/Curve
Needle Colour	Silver/Black
Needle Length	7.9 mm – 70 mm
Needle Wire Diameter	0.20 mm – 1.55 mm

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Certificate History

Date	Reference Number	Action
03 April 2009	10096448	First issue.
07 September 2009	10108867	Change of sterilization cycle from the current Primary Terminal sterilization Cycle ”B” to EO 1st High Temperature Cycle “X”.
30 September 2009	10108540	Manufacturing transfer to Kirkton, Scotland.
15 January 2013	10136503 10136226	Change of legal manufacturer address. Administrative update to the supplementary page for clarity only. Administrative update to certificate format. Change of certificate scope from “ PDS Plus Suture with Triclosan” to “PDS™ Plus Antibacterial (polydioxanone) Suture”. Addition of alternative manufacturing site for dosing Triclosan (Kirkton, Scotland), M5 review.
28 March 2014	10145608	Certificate renewal.
03 March 2015	10152066	Introduction of Motorised Suture Winding Process at Livingston site. Administrative update to the supplementary page for clarity only.

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Date	Reference Number	Action
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.
08 February 2016	10156649	Review of updated IFU and Labelling.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).
26 April 2016	10161088	Addition of three (3) new product codes D10178, D10179 and D10180
03 August 2016	10162190	Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
13 March 2017	10165962 10164004	Addition of site capacity to increase suture manufacturing flexibility. Extension to Needle Wire Diameter and Needle Length range.
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
29 August 2017	8673594	Certificate Renewal. Review of New UPLC testing method as alterative to HPLC testing method.

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Date	Reference Number	Action
10 October 2017	8680077	Addition of manufacturing capacity for a subset of product codes at Ethicon Inc., Juarez, Mexico.
19 June 2018	8940345	Addition of Athens, GA Suture Raw Material Manufacturing facility for sizes Metric 1.5 (USP 4-0), Metric 2 (USP 3-0) and Metric 3 (USP 2-0).
21 August 2018	8996972	Addition of product codes (Project Vantage).
07 December 2018	9640471	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles and administrative update to the suture characteristics table.
04 February 2019	8748451	Review of PDO monomer supplier change.
02 March 2019	8952310	Traceable to NB 0086.
09 September 2019	9658008 9685108	Retrofit of sterilization equipment on the SS1 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization utilizing the X Cycle. Packaging equipment change from HOFM to FIFM3 for foil packaging and primary sealing at the Ethicon, Inc. San Angelo, TX facility. Administrative update to the supplementary page to include the device classification and intended purpose.

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Date	Reference Number	Action
05 March 2020	9690363	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	9689398	Manual stake swage change at the Ethicon, Inc. (Juarez) manufacturing facility.
Current	3218348	Certificate renewal. Removal of indication for "ophthalmic surgery (other than in contact with cornea and sclera)"

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Supplementary Information to CE 536533 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: **Johnson & Johnson International**
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Date: 30 June 2022

Changes Approved:

Date	Reference Number	Action
06 January 2022	3513637	Conversion of the SS2 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization of absorbable products utilizing the X Cycle.
28 February 2022	3297412	Shelf-life increase from 2 years to 4.5 years for PDS™ Plus Antibacterial (polydioxanone) Suture
27 April 2022	3562181	Triclosan Shelf Life Extension from 5 years to 7 years
30 June 2022	3477751	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

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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 536533	93/42/EEC Annex II Section 4	3477751	Addition of the Janssen Pharmaceutical, Athens GA site as a raw material supplier of P-Dioxanone monomer used in the manufacture of PDS Plus Antibacterial (polydioxanone) Suture by Johnson & Johnson International.

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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