EC Design-Examination Certificate

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

No. **CE 00414**

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

In respect of:

PDS™ II (Polydioxanone) Monofilament Suture, Dyed and Undyed

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: **1994-12-12** Date: **2020-06-02** Expiry Date: **2024-05-26**

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Product: 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	7, 10 cm(with Absolok), 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	Absolok Clips, Ethi-Endo-suture Set

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Suture Characteristics	**Range**
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight/Curve
Needle Color	Silver/ Black
Needle Length	6 mm - 110 mm
Needle Wire Diameter	0.15 mm – 1.44 mm

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Certificate History

Date	Reference Number	Action
12 December 1994	ME000541	Original issue.
04 April 1995	ME000738	Reissue, change of product.
22 November 1996	ME000739	Change of certificate format.
12 September 1997	MD000283	Change of company name.
05 January 1998	MD000338	Extension to scope.
13 December 1999	MD000483	Certificate Renewal.
02 September 2002	10041917	Change of address.
29 May 2003	10050292	Change to packaging.
08 July 2003	10051235	"PANACRYL Synthetic absorbable Suture" removed from scope and change to sterilization EtO cycle, correction to Reference Number dated 29 May 2003 from 10050294 to 10050292.
18 September 2003	10052611	Tyvek vent Eto sterilization amendment.
29 June 2004	10060179	Change of packaging, removal of catgut sutures.

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Certificate History

Date	Reference Number	Action
06 December 2004	10063166	Certificate renewal.
12 January 2010	10110638	Certificate renewal.
06 September 2012	10136505	Change of address.
08 April 2014	10145788	Administrative update to address format. Administrative update to supplementary page information. Administrative change of device name. Review of Flexible Automated Swage machine at Livingston Site.
05 November 2014	10151486	Administrative update to supplementary page table. Certificate renewal.
22 June 2015	10151489	Administrative update to supplementary page information. Review of updated labels and IFU.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.

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Date	Reference Number	Action
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.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
19 June 2018	8940352	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).
06 December 2018	9640462	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
04 February 2019	8748448	Review of PDO monomer supplier change.
02 March 2019	8952310	Traceable to NB 0086.

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13 September 2019	9714693	Certificate Renewal. Administrative update to supplementary information to include device class and indication.
05 February 2020	9690186	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.
Current	9688754	Manual stake swage change at the Ethicon, Inc. (Juarez) manufacturing facility.

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By Royal Charter

Supplementary Information to CE 00414 - 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	3477740	Review of Janssen Pharmaceutical, Athens GA as an additional raw material manufacturer and supplier of P-Dioxanone monomer.

Inspiring trust for a more resilient world.

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 00414	93/42/EEC Annex II Section 4	3477740	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 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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