EC Design-Examination Certificate

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

No. **CE 518537**

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

In respect of:

MONOCRYL™ Plus Antibacterial Poliglecaprone-25 (Monofilament), Sterile Synthetic Absorbable Surgical 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: **2007-05-21** Date: **2021-03-31** Expiry Date: **2024-05-26**

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MONOCRYL™ Plus Antibacterial Poliglecaprone -25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture from within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation where an absorbable material is indicated:

Suture Characteristics	**Range**
Suture Material	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 – 90 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet #2
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
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 Color	Silver/Black
Needle Length	10 – 60.3 mm
Needle Wire Diameter	0.25 – 1.3 mm

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Certificate History

Date	Reference Number	Action
21 May 2007	10081198	First issue.
29 January 2008	10092471	Shelf life extension to 2 years. Suture size designation as USP removed on Supplementary Information page.
25 June 2008	10096038	Change to needle wire diameter and needle length. Additional manufacturing site added.
17 May 2012	10133961	Certificate renewal. Administrative update to supplementary page product information.
06 September 2012	10136503	Change of legal manufacturer address. Administrative update to the supplementary page for clarity only. Administrative update to certificate format.
15 January 2013	10136225	Correction of typo in reference number of June 2008 review. Addition of alternative manufacturing site for dosing Triclosan (Kirkton, Scotland).

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Date	Reference Number	Action
03 March 2015	10152066	Introduction of Motorised Suture Winding Process at Livingston site. Administrative update to the supplementary page for clarity only.
04 December 2015	10153616	Addition of CERBERUS needle coating type and CERBERUS coating process in Norderstedt, Germany. Addition of Needle Master File.
01 February 2016	10156652	Review of updated Labels and IFU.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).
18 October 2016	10162980	Addition of harmonised product codes and update to IFU and labelling at Kirkton (VANTAGE). Administrative updates to Supplementary Page information. Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.
12 December 2016	10166514	Update to Indication for Use and labelling for global product codes (VANTAGE). Administrative change to supplementary page.
07 February 2017	10167383	Addition CERBERUS coating process at Ethicon Cornelia, GA.

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Date	Reference Number	Action
13 March 2017	10165960	Addition of site capacity to increase suture manufacturing flexibility.
17 May 2017	10167668	Certificate renewal. Addition of 'black' to needle color.
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
19 June 2018	8899458	Addition of Athens, GA Suture Raw Material Manufacturing Facility for sizes Metric 1.5 (USP 4-0) and Metric 1 (USP 5-0).
05 December 2018	9640470	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
10 September 2019	9731861	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 the device classification and intended purpose.

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Date	Reference Number	Action
05 March 2020	9690365	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	9689394	Manual stake swage change at the Ethicon, Inc. (Juarez) manufacturing facility.
14 October 2020	3218667	Process change to utilize Ultra Performance Liquid Chromatography (UPLC) instrument method to test the triclosan concentration of the post-sterile Plus sutures. Certificate renewal.

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Date	Reference Number	Action
Current	3282147	Addition of new *in-vitro* claim for effectiveness of MONOCRYL™ Plus Antibacterial Suture against additional organism (*Enterobacter cloacae*). Labelling change to increase upper permitted storage temperature from 25°C to 30°C. Branding change on labelling to allow for easier distinction between MONOCRYL™ Suture and MONOCRYL™ Plus Antibacterial Suture.

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Supplementary Information to CE 518537 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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Date: 27 April 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.
27 April 2022	3563109	Triclosan Shelf Life Extension from 5 years to 7 years

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27 April 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 518537	93/42/EEC Annex II Section 4	3563109	Triclosan Shelf Life Extension from 5 years to 7 years

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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