

EC Design-Examination Certificate

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

No.**CE 73804**

Issued To:

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

In respect of:

Coated VICRYL™ PLUS Antibacterial (Polyglactin 910) 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: **2004-09-17**Date: **2021-05-07**Expiry Date: **2023-07-04**

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Page 1 of 7

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.

A member of BSI Group of Companies.

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Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture from within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation. The safety and effectiveness of Coated VICRYL™ Plus Antibacterial sutures in cardiovascular tissue, ophthalmic surgery and neurological tissue have not been established.

SUTURE CHARACTERISTICS	RANGE
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	1.0 – 5.0 (metric)
Suture Length	5cm – 250cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and lactide, calcium stearate)
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels (ug/m)	≤ 275 µg/m
Accessories to suture type	N/A
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420, 420 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, MULTIPASS

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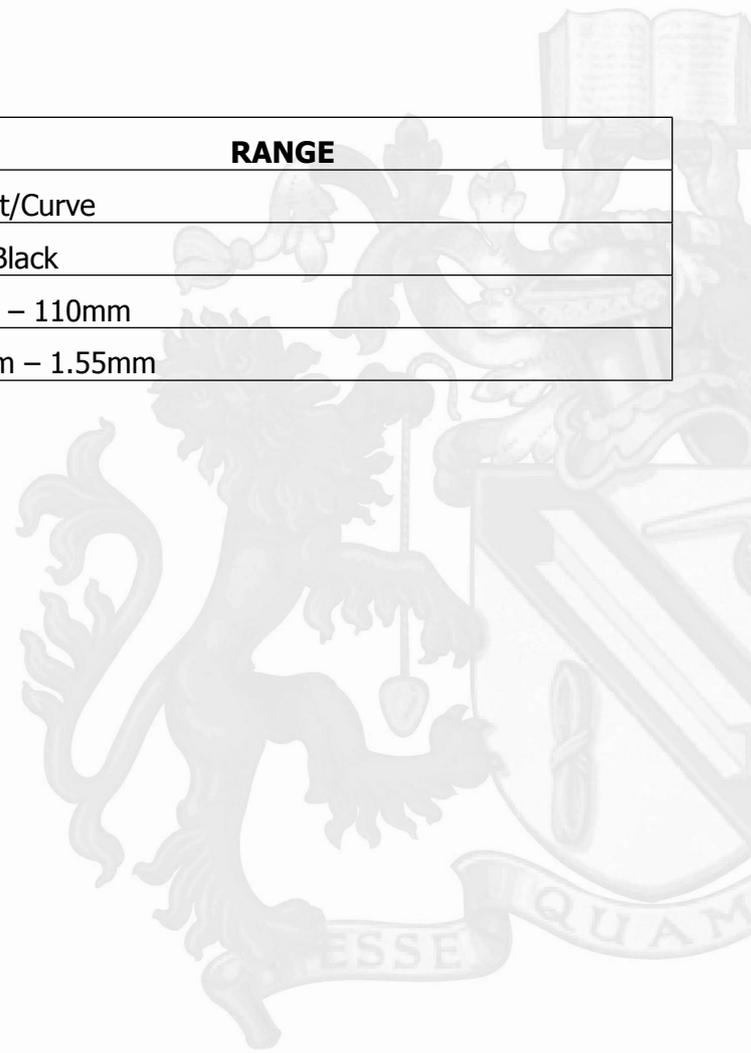
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SUTURE CHARACTERISTICS	RANGE
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Length	3.5mm – 110mm
Needle Wire Diameter	0.10mm – 1.55mm



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Certificate History

Date	Reference Number	Action
17 September 2004	10049224	First issue.
23 December 2004	10063712	Addition of size 4 and 5 sutures.
01 March 2005	10065810	Extension to shelf life of Vicryl Plus suture which contains Triclosan from 2 years to 3.0 years.
20 June 2005	10065925	Transfer of coating process to Hamburg Germany.
12 April 2006	10068862	Changing the upper Triclosan limit to 270 µg/m.
02 June 2006	10078773	Change to pack configuration (addition of Multipack) and minor increase in upper Triclosan limit to 275 µg/m.
09 September 2009	10109409	Certificate renewal.
30 October 2012	10136503	Change of legal manufacturer address. Administrative update to the supplementary page for clarity only. Administrative update to certificate format.

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Date	Reference Number	Action
08 July 2014	10144769	Change of device name to Coated VICRYL™ Plus Antibacterial Suture. Review of updated labelling and instructions for use. Administrative update to certificate format.
11 September 2014	10149209	Certificate renewal. Administrative corrections to product details in supplementary page.
04 December 2015	10153616	Addition of Needle Master File.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). Administrative updates to scope and supplementary page.
03 August 2016	10162190	Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package. Administrative update to supplemental information.
16 November 2016	10166522	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 4/0, 2/0, 1 (Metric 1.5, 3, 4)(56 Denier, Dyed).
22 December 2016	10153556	Multipack Folder and Coating Solution Change for product codes VCP1219H and VCPV967H.

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Date	Reference Number	Action
05 May 2017	10169583	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 9-0 (Metric 0.3) (8 Denier, Dyed), USP 6-0 (Metric 0.7) (14 Denier, Un-Dyed), USP 3-0 (Metric 2) (52 Denier, Dyed & Un-Dyed) and USP 4/0, 2/0, 1 (Metric 1.5, 3, 4) (56 Denier, Un-Dyed).
29 June 2017	8742925	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing for sizes USP 8-0 (Metric 0.4) (10 Denier, Dyed), USP 6-0 (Metric 0.7) (14 Denier, Dyed), USP 7-0 (Metric 0.5) (16 Denier, Dyed & Un-Dyed), USP 5-0 (Metric 1) (28 Denier, Dyed), and USP 0 (Metric 3.5) (80 Denier, Dyed & Un-Dyed).
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
29 June 2018	8942302	Certificate Renewal.
05 December 2018	9640469	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
12 September 2019	9685106	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
17 April 2020	9690319	<p>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.</p> <p>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.</p>
17 September 2020	9688925	Manual stake swage change at the Ethicon, Inc. (Juarez) manufacturing facility.
	9698321	Supplier change for Labyrinth 4Up and 5Up Trays. Increase of the 5Up tray height from 2.4 mm to 2.55 mm. Minor dimensional adaptations for the Labyrinth 4Up tray.
	3203047	Line extension and addition of new needle sales types at Johnson & Johnson Medical GmbH (Norderstedt, Germany).
Current	3366683	<p>Laminated foil packaging supplier change form Novelis Deutschland GmbH to Amcor Flexibles Transpac BVBA</p> <p>Transfer of suture packaging process of the 4-up cavities from Foilline 18 to Foilline 17 at the Johnson & Johnson Medical GmbH Norderstedt facility for increased capacity.</p>

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Supplementary Information to CE 73804 - 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
27 April 2022	3563100	Triclosan Shelf Life Extension from 5 years to 7 years

27 April 2022

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To whom it may concern,

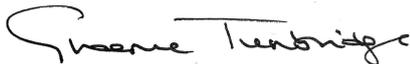
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 73804	93/42/EEC Annex II Section 4	3563100	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