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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

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EC Design-Examination Certificate

Supplementary Information to CE 73804

Issued To:

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BE-1831 Diegem
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Product: Coated VICRYL™ PLUS Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture

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

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

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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

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

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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.

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

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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.

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

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Supplementary Information to CE 73804

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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.
Current	8942302	Certificate Renewal.

First Issued: **2004-09-17** Date: **2018-06-29** Expiry Date: **2023-07-04**

EC Certificate - Full Quality Assurance System

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

No. **CE 589698**

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

In respect of:

Design, development and manufacture of devices as detailed in the Supplementary Information

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2012-09-06** Date: **2019-03-02** Expiry Date: **2022-07-07**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 589698

Issued To:

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

Cords (Absorbable, Sterile)	Surgically Implantable Plugs (Partially Absorbable & Absorbable, Sterile)
Pledgets (Sterile)	Surgical Support Tapes (Absorbable and Non Absorbable, Sterile)
Surgical Bone Wax (Sterile)	Sutures and ligatures (Needled and non-needled, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic , medicated and non-medicated) (Sterile)
Surgical Mesh Systems (Non-absorbable, Sterile)	Fixation Clips (Sterile)
Pelvic organ prolapse urogynaecological surgical mesh (sterile)	Surgical Meshes (Partially Absorbable, Absorbable and Non-Absorbable, Sterile)
Surgically Implantable Pins & Plates (Absorbable, Sterile)	

First Issued: **2012-09-06** Date: **2019-03-02** Expiry Date: **2022-07-07**

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 589698**
Date:	**2019-03-02**
Issued To:	**Johnson & Johnson International** **c/o European Logistics Centre** **Leonardo Da Vincilaan 15** **BE-1831 Diegem** **Belgium**

Subcontractor:	**Service(s) supplied**
Ethicon Inc 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	**ETO Sterilization** **Manufacture**
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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Date:	**2019-03-02**
Issued To:	**Johnson & Johnson International** **c/o European Logistics Centre** **Leonardo Da Vincilaan 15** **BE-1831 Diegem** **Belgium**

Subcontractor:	**Service(s) supplied**
Ethicon Inc Route 22 West Somerville NJ 08876-0151 USA	**Design**
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	**Manufacture** **Packaging**
Johnson & Johnson do Brasil Indústria e Comércio de Productos Para Saúde Ltda. Rod. Presiodente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	**ETO Sterilization** **Gamma Sterilization** **Manufacture**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 589698**
Date:	**2019-03-02**
Issued To:	**Johnson & Johnson International** **c/o European Logistics Centre** **Leonardo Da Vincilaan 15** **BE-1831 Diegem** **Belgium**

Subcontractor:	**Service(s) supplied**
Johnson & Johnson MEDICAL GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	**Design** **ETO Sterilization** **Gamma Sterilization** **Manufacture**
Johnson & Johnson Medical Limited Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	**Gamma Sterilization** **Manufacture**
The Secant Group, LLC 195 O'Neill Drive Quakertown Pennsylvania 18951 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 589698**

Date: **2019-03-02**

Issued To: **Johnson & Johnson International**
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Date	Reference Number	Action
06 September 2012	7867743	First issue based on CE 01651.
30 October 2012	7909339	Addition of 'Ethicon Inc, Chihuahua' and 'Ethicon Inc, San Angelo' as significant subcontractors.
14 May 2013	7983862	Correction of expiry date to 7 Jul 2017. Addition of 'Pelvic organ prolapse urogynaecological surgical mesh (sterile)' and 'Sternal fixation system (non-sterile)'.
19 June 2014	8138505	Addition of Partially Absorbable Plugs to Scope and removal of Ethicon S.A.S. France as significant subcontractor due to site closure.
27 January 2015	8254791	Removal of Wound Closure Devices (Sterile) & Sternal Fixation System (Non Sterile) & Addition of Fixation Clips (Sterile) to supplementary table.
17 March 2015	8297184	Addition of Partially Absorbable Surgical Meshes to scope.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 589698**

Date: **2019-03-02**

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Date	Reference Number	Action
5 July 2017	8713813	Certificate Renewal. Removal of Temporary Cardiac Pacing Wires (Sterile) from scope. Addition of Secant Manufacturing as a significant subcontractor. Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing. Addition of 'Packaging' as activity for Ethicon Inc., Ciudad Juarez, Mexico. Change of activity to 'ETO Sterilisation' from 'Sterilisation' for Ethicon Inc., San Angelo, Texas. Addition of 'Ethicon, Inc, Georgia' and 'The Secan Group, LLC, Pennsylvania' as significant subcontractors.
5 December 2017	8802715	Addition of significant subcontractor Johnson & Johnson do Brasil Industria for manufacture and sterilization.
Current	8952310	Traceable to NB 0086. Johnson & Johnson do Brasil Indústria e Comércio de Productos Para Saúde Ltda, São Paulo, 12240-908 from Sterilization to Gamma and ETO Sterilization. Johnson & Johnson MEDICAL GmbH, Norderstedt, 22851 from Sterilization to Gamma and ETO Sterilization. Johnson & Johnson Medical Limited, Livingston, EH54 7AT from Sterilization to Gamma Sterilization.