

# EC Design-Examination Certificate

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

**No.****CE 73804**

## Issued To:

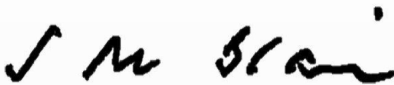
**Johnson & Johnson International  
c/o European Logistics Centre  
Leonardo Da Vincilaan 15  
BE-1831 Diegem  
Belgium**

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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Page 1 of 6

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.

# EC Design-Examination Certificate

## Supplementary Information to CE 73804

Issued To:

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

**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   |

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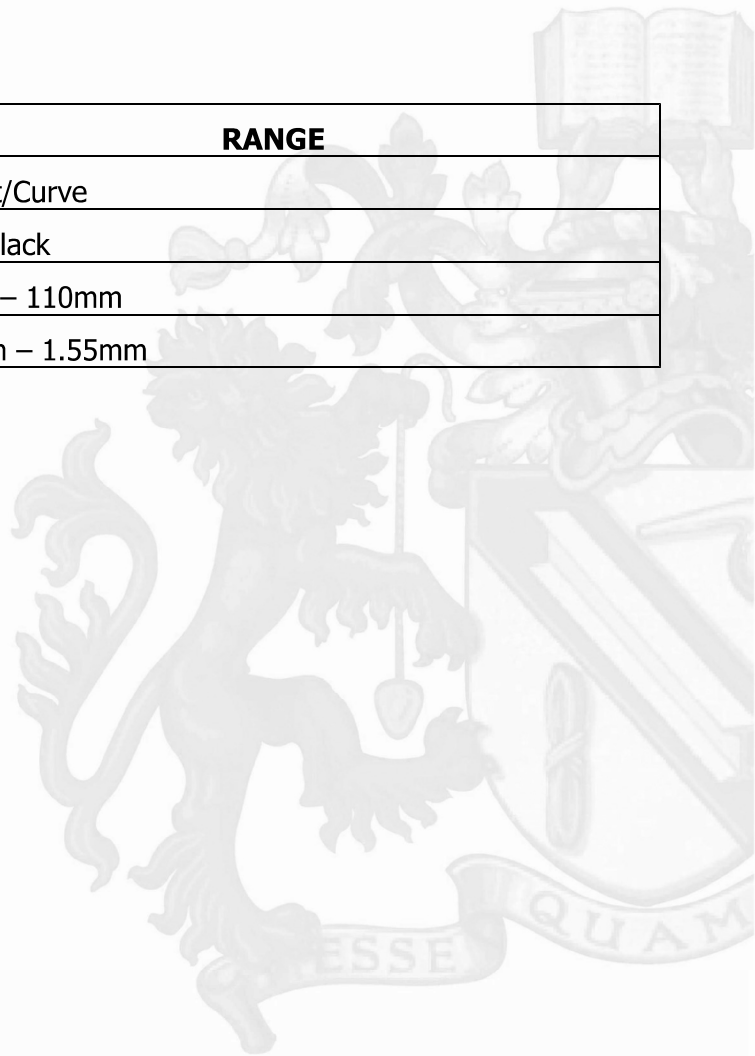
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## Supplementary Information to CE 73804

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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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# EC Design-Examination Certificate

## Supplementary Information to CE 73804

Issued To:

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Belgium**

## 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.<br>Administrative update to the supplementary page for clarity only.<br>Administrative update to certificate format. |

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# EC Design-Examination Certificate

## Supplementary Information to CE 73804

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| Date              | Reference Number | Action  |
|-------------------|------------------|---|
| 08 July 2014      | 10144769         | Change of device name to Coated VICRYL™ Plus Antibacterial Suture.<br>Review of updated labelling and instructions for use.<br>Administrative update to certificate format. |
| 11 September 2014 | 10149209         | Certificate renewal.<br>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®).<br>Administrative updates to scope and supplementary page.                                    |
| 03 August 2016    | 10162190         | Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.<br>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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# EC Design-Examination Certificate

## Supplementary Information to CE 73804

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Belgium**

| 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**

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Expiry Date: **2023-07-04**

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# EC Certificate - Full Quality Assurance System

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

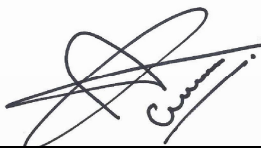
**No.** CE 589698  
**Issued To:** **Johnson & Johnson International**  
**c/o European Logistics Centre**  
**Leonardo Da Vincilaan 15**  
**BE-1831 Diegem**  
**Belgium**

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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Page 1 of 2

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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.

# 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-needed, 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**

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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**

| <b>Subcontractor:</b>   | <b>Service(s) supplied</b>               |
|---|--|
| Ethicon Inc<br>1420 Olympic Drive<br>Athens<br>Georgia<br>30601<br>USA    | <b>Manufacture</b>                       |
| Ethicon Inc<br>3348 Pulliam Street<br>San Angelo<br>Texas<br>76905<br>USA | <b>ETO Sterilization<br/>Manufacture</b> |
| Ethicon Inc<br>655 Ethicon Circle<br>Cornelia<br>Georgia<br>30531<br>USA  | <b>Manufacture</b>                       |

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# EC Certificate - Full Quality Assurance System

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

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

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

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# EC Certificate - Full Quality Assurance System Certificate History

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 Date: **2019-03-02**  
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 Leonardo Da Vincilaan 15  
 BE-1831 Diegem  
 Belgium**

| 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.<br>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

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| Date            | Reference Number | Action   |
|-----------------|------------------|--|
| 5 July 2017     | 8713813          | Certificate Renewal.<br>Removal of Temporary Cardiac Pacing Wires (Sterile) from scope.<br>Addition of Secant Manufacturing as a significant subcontractor.<br>Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing.<br>Addition of 'Packaging' as activity for Ethicon Inc., Ciudad Juarez, Mexico.<br>Change of activity to 'ETO Sterilisation' from 'Sterilisation' for Ethicon Inc., San Angelo, Texas.<br>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.<br>Johnson & Johnson do Brasil Indústria e Comércio de Produtos Para Saúde Ltda, São Paulo, 12240-908 from Sterilization to Gamma and ETO Sterilization.<br>Johnson & Johnson MEDICAL GmbH, Norderstedt, 22851 from Sterilization to Gamma and ETO Sterilization.<br>Johnson & Johnson Medical Limited, Livingston, EH54 7AT from Sterilization to Gamma Sterilization.  |

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