By Royal Charter

EC Design-Examination Certificate

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

No. **CE 00584**

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

In respect of:

VICRYL RAPIDE™ (Polyglactin 910) 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: **1995-04-11** Date: **2020-06-23** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 00584

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VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture Needle and Suture combinations from within the following limits are Class III devices, intended for use in soft tissue approximation where only short term wound support is required and where the rapid absorption of the suture would be beneficial. Due to its absorption profile VICRYL RAPIDE™ is useful for skin closure, particularly in pediatric surgery, episiotomies, circumcision and closure of oral mucosa. VICRYL RAPIDE™ is also successfully used in ophthalmic surgery for conjunctival sutures.

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.4 – 4.0 (Metric)
Suture Length	45 cm – 150 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet
Coated/Uncoated	Coated
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, 4310 FB SS and ETHALLOY

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Suture Characteristics	**Range**
Needle Coating	Silicone, MULTIPASS, CERBERUS
Needle Shape	Straight/Curve
Needle Color	Sliver / Black
Needle Length	5.5 mm – 60 mm
Needle Wire Diameter	0.15 mm – 1.27 mm

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Certificate History

Date	Reference Number	Action
11 April 1995	ME000733	Original issue.
15 May 1996		Reissue, wrong directive on original issue.
10 December 1996		Reissue new certificate paper.
12 September 1997	MD000283	Change of company name.
31 March 2000	10013279	Change of product and certificate renewal.
02 September 2002	10041917	Change of address.
29 May 2003	10050294	Change to packaging.
08 July 2003	10051235	Change to sterilization ETO cycle.
19 August 2003	10051066	Change in packaging (peelable foil) and sterilization process (Tyvec vent).
10 October 2003	10051025	Add Vicryl Rapide with NVC coating to the product line.
14 April 2005	10067084	Certificate renewal.

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Date	Reference Number	Action
12 July 2010	10116432	Certificate renewal.
22 November 2010	10118975	Review of change in supplier of GMS from Stephen Company to Hallstar Company and change in copolymer drying process.
06 September 2012	10136503	Change of address.
09 April 2015	10153733	Certificate renewal. Updates to IFU/Artwork. Administrative change to scope wording.
04 December 2015	10153616	Addition of Needle Master File.
07 February 2017	10167383	Addition of CERBERUS needle coating type and CERBERUS coating process at Ethicon Cornelia, Georgia.
05 December 2018	9640465	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
30 March 2020	9789824	Certificate renewal.

First Issued: **1995-04-11** Date: **2020-06-23** Expiry Date: **2024-05-26**

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Date	Reference Number	Action
Current	9690189	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.
	3007684	Supplier change for Labyrinth 4Up and 5Up Trays. Increase of the Labyrinth 5up tray height from 2.4 mm to 2.55 mm. Minor dimensional adaptations for the Labyrinth 4up tray.
		Administrative update to the supplementary page to add the device name, classification and intended use.

First Issued: **1995-04-11** Date: **2020-06-23** Expiry Date: **2024-05-26**

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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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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**

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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**
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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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 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

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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.