EC Design-Examination Certificate

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

No. **CE 00480**

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

In respect of:

PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-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: **1995-01-20** Date: **2019-04-04** Expiry Date: **2024-04-03**

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EC Design-Examination Certificate

Supplementary Information to CE 00480

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PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-absorbable Surgical Suture from within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures:

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.4 - 4.0 (Metric)
Suture Length	45 cm - 90 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Blue
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Tubing, Ethisorb Pledgets
Needled/Non-Needled	Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, and ETHALLOY

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Suture Characteristics	**Range**
Needle Coating	CERBERUS, Silicone, MULTIPASS + Additional Coating of Silicone (Double Dip)
Needle Shape	Curve
Needle Color	Silver/Black
Needle Length	6.5 mm – 90 mm
Needle Wire Diameter	0.152 mm – 1.27 mm

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ENDOLOOP™ Characteristics	**Range**
Suture Gauge Size	3 (Metric)
Suture Length	90 cm
Suture Dyed / Undyed	Dyed (Blue)
Cannula Specifications	Material: Nylon 11 Length: 38 cm OD: 3.9 mm

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Issued To:

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Certificate History

Date	Reference Number	Action
20 January 1995	MD 000736	First Issued.
04 April 1995	MD 000737	Reissue.
22 November 1996		Reissue, new certificate paper.
12 September 1997	MD 000283	Change of company name.
20 January 2000	10010077	Removal of ETHIBOND®, Renewal.
02 September 2002	10041917	Change of company address.
29 May 2003	10050294	Change to sterilisation cycle.
08 July 2003	10051235	Change to 4terilisation ETO cycle.
31 October 2003		Correction to expiration date.
06 February 2004	10054043	Change in packaging (peelable foil) and sterilisation process (Tyvek vent).
29 June 2004	10060179	Change of Packaging.
17 January 2005	10063739	Certificate renewal.

First Issued: **1995-01-20** Date: **2019-04-04** Expiry Date: **2024-04-03**

EC Design-Examination Certificate

Supplementary Information to CE 00480

Issued To:

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Certificate History

Date	Reference Number	Action
18 March 2010	10115664	Certificate renewal.
08 August 2012	10135623	Update of wildcard references on certificate supplementary page and packaging and sterilization transfer to Livingston, UK facility for devices packaged in procedure packs.
30 October 2012	10136503	Change of legal manufacturer address.
16 January 2015	10146322	Certificate renewal. Administrative update to supplementary pages.
04 December 2015	10153616	Addition of MULTIPASS + Additional Coating of Silicone (Double Dip) needle coating type Addition of Needle Master File.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®). Administrative update to scope.
12 January 2017	10153298	Addition of ENDOLOOP. Administrative change to supplementary page.
07 February 2017	10167383	Addition of CERBERUS needle coating type and CERBERUS coating process at Ethicon Cornelia, Georgia. Administrative correction to ENDOLOOP characteristics table.

First Issued: **1995-01-20** Date: **2019-04-04** Expiry Date: **2024-04-03**

EC Design-Examination Certificate

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Date	Reference Number	Action
10 November 2017	8794404	Addition of Ethicon Athens, GA for the raw material supply of PROLENE Sutures for sizes: 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, and 5 (Metric).
05 December 2018	9640463	Change to blackening process for 4310 Stainless Steel VISI-BLACK™ Needles.
02 March 2019	8952310	Traceable to NB 0086.
Current	9687840	Certificate renewal. Administrative update to supplementary page to add the device classification and intended purpose.

First Issued: **1995-01-20** Date: **2019-04-04** Expiry Date: **2024-04-03**

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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**

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

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 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**

Issued To: **Johnson & Johnson International**
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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.