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**

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

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**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

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

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

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.

EC Design-Examination Certificate

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

No. **CE 01305**

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

In respect of:

MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile Synthetic 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: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01305

Issued To:

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

MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile Synthetic Absorbable Surgical Suture within the following limits are Class III devices, intended for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery:

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 - 250 cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (If dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	N/A
Needled/Non-Needled	Non-Needled/ Needled (also available with CONTROL RELEASE™ needles)
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS and ETHALLOY

First Issued: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01305

Issued To:

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

Suture Characteristics	**Range**
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Black / Silver
Needle Length	8 mm – 70 mm
Needle Wire Diameter	0.25mm – 1.45mm

First Issued: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01305

Issued To:

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

Certificate History

Date	Reference Number	Action
12 June 1995	MD000005	First Issued Certificate Number 0656. MONOCRYL® POLIGLECAPRONE 25 undyed synthetic absorbable suture.
19 February 1996	MD000092	Extension to scope.
06 March 1996	MD000131	First Issued Certificate Number 1231. MONOCRYL® POLIGLECAPRONE 25 violet dyed synthetic absorbable suture.
09 May 1996	MD000005 MD000092 MD000131 MD000145	Original issue of Certificate CE 01305 bringing together previous two certificates.
10 December 1996		Change of certificate paper.
12 September 1997	MD000283	Change of product and company name.
17 August 1998	MD000283-1	Change of product.
09 May 2001	10026219	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.

First Issued: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01305

Issued To:

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

Date	Reference Number	Action
29 June 2004	10060179	Change in packaging.
30 July 2004	10061285	Ethicon GmbH added as an additional manufacturer.
03 May 2006	10078920	Certificate renewal.
19 May 2011	10123380	Modification of scope to align with CE 01075 and more specifically identify the device. Certificate Renewal.
06 September 2012	10136503	Change of address.
05 March 2014	10144913	Administrative update to supplementary page details. Review of Flexible Automated Swage Process at Livingston facility.
07 November 2014	10151494	Certificate renewal. Administrative update to supplementary page.
04 December 2015	10153616	Addition of CERBERUS needle coating type and CERBERUS coating process in Norderstedt, Germany. Addition of Needle Master File.
19 January 2016	10155454	Change of labelling for storage conditions and other administrative modifications.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).

First Issued: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 01305

Issued To:

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

Date	Reference Number	Action
03 August 2016	10162190	Installation of New Packaging Equipment GIFM1 and Ink Change on the Foil Package.
19 September 2016	10162980	Addition of harmonised product codes and update to IFU and labelling at Ciudad Juarez and Kirkton (VANTAGE). Administrative update to certificate scope. Administrative updates to Supplementary Page information.
12 December 2016	10166514	Update to Indication for Use and labelling for global product codes (VANTAGE).
07 February 2017	10167383	Addition CERBERUS coating process at Ethicon Cornelia, GA.
11 August 2017	8716374	Review of BC5 blanking and cartoning machine at San Angelo, TX site.
19 June 2018	8899451	Addition of Athens, GA Suture Raw Material Manufacturing Facility for sizes Metric 1.5 (USP 4-0) and Metric 1 (USP 5-0).
02 March 2019	8952310	Traceable to NB 0086.
Current	9716908	Certificate Renewal. Scope extension to needle wire diameter to increase the validated range from 0.39mm-1.45mm to 0.25mm-1.45mm. Administrative update to the supplementary page to include the device classification and intended use.

First Issued: **1996-05-09** Date: **2019-08-30** Expiry Date: **2024-05-26**

...making excellence a habit.™