By Royal Charter

EC Design-Examination Certificate

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

No. **CE 01722**

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

In respect of:

MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-Absorbable Sutures

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: **1996-07-11** Date: **2020-06-28** Expiry Date: **2024-05-26**

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MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-Absorbable Surgical Suture Needle and Suture combinations 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 neurological procedures.

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture GauQe Size	1.0 - 8.0 (Metric)
Suture Length	30cm - 250cm
Suture Dyed/Undyed	Dyed/Undyed
Suture Color (if dyed)	Black/Blue
Coated/Uncoated	Coated/Uncoated
Multifilament/Monofilament	Multifilament
Contains Antimicrobials (Yes/No)	No
Accessories to suture type	N/A
Needle material	4310 SS
Needle coating	Silicone, CERBERUS, MULTIPASS
Needle shape	Straight/Curve

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Suture Characteristics	Range
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ Needles)/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Length	13mm – 22mm
Needle Wire Diameter	0.46mm – 0.66mm

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Certificate History

Date	Reference Number	Action
11 July 1996	MD000146	Certificate first issued.
12 August 1997	MD000279	New certificate format.
12 September 1997	MD000283	Change of company name to Johnson & Johnson International and address.
11 July 2001	10028665	Certificate renewal and inclusion of suture ranges.
30 October 2001	10028665	Correction to report numbers.
02 September 2002	10041917	Change of address.
29 June 2004	10060179	Change of packaging and certificate new format.
04 July 2006	10079988	Certificate renewal.

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Date	Reference Number	Action
07 July 2011	10123652	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.
06 September 2012	10136503	Change of address. Administrative update to certificate format.
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS and CERBERUS coating process at Norderstedt, Germany. Addition of Needle Master File.
27 January 2016	10158160	Change of labelling for the removal of special storage conditions and updates to the IFU content. Administrative updates to supplementary information.
25 June 2016	10161649	Certificate renewal. Administrative updates to supplementary page information. Addition of the word 'sterile' to scope.
07 February 2017	10167383	Addition of CERBERUS coating process at Ethicon Cornelia, Georgia.
02 March 2019	8952310	Traceable to NB 0086.

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Supplementary Information to CE 01722

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Date	Reference Number	Action
Current	9690318	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.
	9789285	Certificate Renewal.
		Administration update to supplementary page to include the device name, classification and intended use.

First Issued: **1996-07-11** Date: **2020-06-28** 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

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Supplementary Information to CE 589698

Issued To:

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Cords (Absorbable, Sterile)	Surgically Implantable Plugs (Partially Absorbable & Absorbable, Sterile)
Pledgets (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 Bone Wax (Sterile)	Fixation Clips (Sterile)
Surgical Mesh Systems (Non-absorbable, Sterile)	Surgical Meshes (Partially Absorbable, Absorbable and Non-Absorbable, Sterile)
Pelvic organ prolapse urogynaecological surgical mesh (sterile)	
Surgically Implantable Plates (Absorbable, Sterile)	

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

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Supplementary Information to CE 589698

Issued To:

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Device Code	Device name	Intended purpose per IFU
Class III		
---	PDS™ Cord	See CE 508562
---	PDS™ Cord II	See CE 508560
---	LAPRA-TY™ II Clips	See CE 511911
---	ETHISORB™ Dura Patch/Pledget/Patch Type 6	See CE 507823
---	ULTRAPRO™ Plug Product Family	See CE 515809
---	PDS™ Plate	See CE 511913
---	ULTRAPRO™ Hernia System	See CE 505757
---	PHYSIOMESH™ Open Flexible Composite Mesh	See CE 565501
---	PROCEED™ Ventral Patch	See CE 543381
---	VICRYL™ (Polyglactin 910) Knitted Mesh	See CE 509893
---	VICRYL™ Mesh Bag	See CE 509896

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

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Device Code	Device name	Intended purpose per IFU
Class III		
---	ETHIBOND EXCEL™ Polybutylate Coated Polyester Sterile Synthetic Non-absorbable Surgical Sutures	See CE 00819
---	ETHILON™ Polyamide 6 or Polyamide 6,6 Sterile Synthetic Non-Absorbable Surgical Sutures	See CE 01326
---	MERSILENE™ and MERSUTURE™ Braided and Monofilament Synthetic Non-absorbable Sutures – Green Dyed and Undyed	See CE 01130
---	MERSILK™ and PERMA-HAND™ Braided Silk and Virgin Silk Sterile Non-absorbable Sutures	See CE 01722
---	MONOCRYL™ Poliglecaprone 25 (Monofilament) Sterile Synthetic Absorbable Surgical Sutures	See CE 01305
---	MONOCRYL™ Plus Antibacterial Poliglecaprone 25 (Monofilament), Sterile Synthetic Absorbable Surgical Sutures	See CE 518537

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 589698

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Device Code	Device name	Intended purpose per IFU
Class III		
---	NUROLON™ Braided Polyamide 6,6 Sterile Synthetic Non-Absorbable Surgical Sutures	See CE 00515
---	PDS™ II (Polydioxanone) Monofilament Sutures, Dyed and Undyed	See CE 00414
---	PDS™ Plus Antibacterial (Polydioxanone) Sutures	See CE 536533
---	PROLENE™ Polypropylene (Monofilament) Sterile, Synthetic Non-absorbable Surgical Sutures	See CE 00480
---	Coated VICRYL™ Plus Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Sutures	See CE 73804
---	VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Sutures	See CE 00585
---	PROCEED™ Surgical Mesh	See CE 699129
---	ETHISORB™ Medullary Plug	See CE 507822

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

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Device Code	Device name	Intended purpose per IFU
Class III		
---	VICRYL™ Rapide (Polyglactin 910) Synthetic Absorbable Sutures	See CE 00584
Class IIb		
59676	ARTISYN™-Y Shaped Mesh	ARTISYN™-Y Shaped Mesh is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.
59676	Ethicon BONE WAX	Bone Wax is intended for use for the control of bleeding from the divided, drilled or chipped edges of bone by physically plugging the osseous canals which contain the bleeding capillaries.

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Device Code	Device name	Intended purpose per IFU
Class IIb		
44756	ULTRAPRO™ Mesh	ULTRAPRO™ Mesh may be used for the repair of hernias or other abdominal fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
44756	ULTRAPRO ADVANCED™ Mesh	ULTRAPRO ADVANCED™ Mesh may be used for the repair of abdominal fascial deficiencies, such as hernias, that require the addition of a reinforcing or bridging material to obtain the desired surgical result.
13904 (Multifilament) 15971 (Monofilament)	SURGICAL STAINLESS STEEL WIRE Suture	SURGICAL STAINLESS STEEL WIRE sutures are for use in abdominal wound closure, hernia repair, sterna closure and orthopedic procedures including cerclage and tendon repair

First Issued: **2012-09-06** Date: **2021-04-30** Expiry Date: **2024-05-26**

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:	**2021-04-30**
Issued To:	**Johnson & Johnson International** **c/o European Logistics Centre** **Leonardo Da Vincilaan 15** **BE-1831 Diegem** **Belgium**

Subcontractor:	**Service(s) supplied**
BASF Grenzach GmbH Koechlinstraβe 1 79639 Grenzach-Whylen Germany	**Medicinal Substances**
Ethicon, Inc. 655 Ethicon Circle Cornelia Georgia 30531 USA	**Manufacture**
Ethicon, Inc. 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Ethicon, Inc. 3348 Pulliam Street San Angelo Texas 76905 USA	**ETO Sterilization** **Manufacture**
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	**Manufacture** **Packaging**
Ethicon, Inc. Route 22 West, P.O. Box 151 Somerville New Jersey 08876-0151 USA	**Design** **Regulatory Compliance**

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	**ETO Sterilization** **Manufacture** **Radiation (Gamma Sterilization)**
Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	**Design** **ETO Sterilization** **Manufacture** **Radiation (Gamma Sterilization)**
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**

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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

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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.
02 March 2019	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 Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 589698**

Date: **2021-04-30**

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Date	Reference Number	Action
30 April 2021	3110448	Certificate Renewal Removal of Surgical Support Tapes (Absorbable and Non Absorbable, Sterile) from scope statement listed in the supplementary information table. Removal of 'Pins' from 'Surgically Implantable Pins & Plates' scope statement listed in the supplementary information table Removal of J&J Limited-Kirkton Campus as critical subcontractor Addition BASF as Medicinal Substance crucial supplier Administrative updates include: Minor updates to names & addresses to critical subcontractors Ethicon, Inc. and J&J Medical GmbH Clarification to the sterilization services supplied (ETO vs. Radiation (Gamma Sterilization)) Addition of 'Regulatory Compliance' to Ethicon, Inc. Somerville site Administrative update to supplementary page device table

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-04-30**

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
09 December 2021	3512365	Removal of stainless steel suture and ETHISORB™ Medullary Plug from certificate.

Inspiring trust for a more resilient world.

09 December 2021

Johnson & Johnson International
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BE-1831 Diegem
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 589698	93/42/EEC Annex II excluding Section 4	3512365	Removal of stainless steel suture and ETHISORB™ Medullary Plug from certificate.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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