EC Certificate - Full Quality Assurance System

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

No. **CE 555605**

Issued To: **Ethicon, LLC**
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

In respect of:

The design, development and manufacture of:
- Sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic, medicated and non-medicated) and associated applicators, bolsters, beads and collars, clips, and pledgets (sterile)
- Tissue Fixation Devices (absorbable and non-absorbable, sterile)
- Surgical Bone Wax (sterile)
- Surgical Support Tapes (non-absorbable, sterile)

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: **2009-11-13** Date: **2019-11-07** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 555605

Issued To:

Ethicon, LLC
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Number	Device Name	Intended purpose per IFU
Class III		
---	VICRYL Suture	See CE 555604
---	MERSILENE Suture and MERSUTURE Suture	See CE 555596
---	MONOCRYL Suture	See CE 555599
---	VICRYL PLUS Antibacterial Suture	See CE 591501
---	PDS II Suture	See CE 555601
---	VICRYL Rapide Suture	See CE 575854
---	ETHIBOND EXCEL Suture	See CE 555593
---	PROLENE Suture	See CE 555603
---	ETHILON Suture	See CE 555595
---	MERSILK and PERMA-HAND Suture	See CE 555597
---	NUROLON Suture	See CE 555600
---	STRATAFIX PDS Plus Knotless Tissue Control Device	See CE 630873

First Issued: **2009-11-13** Date: **2019-11-07** Expiry Date: **2024-05-26**

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Supplementary Information to CE 555605

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Number	Device Name	Intended purpose per IFU
Class III		
---	STRATAFIX Spiral Monocryl Plus Knotless Tissue Control Device	See CE 653647
---	ETHICON SECURESTRAP	See CE 575366
Class IIb		
13904 (Multifilament) 15971 (Monofilament)	Stainless Steel Suture	Stainless Steel Sutures are for use in abdominal wound closure, hernia repair, sterna closure and orthopaedic procedures including cerclage and tendon repair.
46930	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.

First Issued: **2009-11-13** Date: **2019-11-07** Expiry Date: **2024-05-26**

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Number	Device Name	Intended purpose per IFU
Class IIb		
46242	MERSILENE Tape	MERSILENE™ Tape is indicated for circular suture of the cervix. Non-needled tapes are used as retraction and/or fixing tape during surgery.

First Issued: **2009-11-13** Date: **2019-11-07** Expiry Date: **2024-05-26**

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By Royal Charter

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 555605**
Date:	**2019-11-07**
Issued To:	**Ethicon, LLC** **475 C Street** **Los Frailes Industrial Park** **Suite 401** **Guaynabo** **Puerto Rico** **00969** **USA**

Subcontractor:	**Service(s) supplied**
BASF-SE Köchlinstraße 1 Grenzach-Whylen 79639 Germany	**Crucial Supplier** **Medicinal Substances**
Ethicon Endo-Surgery, Inc. 3801 University Boulevard SE Albuquerque, NM 87106 USA	**Radiation (Gamma Sterilization)**
Ethicon Inc 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	**ETO Sterilization** **Manufacture**
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	**Manufacture**
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	**Manufacture** **Packaging**

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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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Subcontractor:	**Service(s) supplied**
Ethicon, Inc. 1000 Route 202 Raritan New Jersey 08869 USA	**Design** **Regulatory Compliance**
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico USA	**Manufacture**
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	**ETO Sterilization**

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

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Radiation (Gamma Sterilization)**
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** **Manufacture** **Packaging** **Radiation (Gamma Sterilization)**
Johnson & Johnson Medical (China) Ltd. No 75 Nangu Zhi Road, Minhang 200245 Shanghai China	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	**EU Representative** **Manufacture**
Nypro Healthcare Baja Inc. 3801 University Blvd SE Albuquerque NM 87106 USA	**Radiation (Gamma Sterilization)**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**

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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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Issued To:	**Ethicon, LLC** **475 C Street** **Los Frailes Industrial Park** **Suite 401** **Guaynabo** **Puerto Rico** **00969** **USA**

Subcontractor:	**Service(s) supplied**
Steris Isomedix Puerto Rico LLC State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 555605**

Date: **2019-11-07**

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Date	Reference Number	Action
13 November 2009	7449449	First issue.
23 May 2012	7829754	Update of certificate format. Administrative change to scope language for sutures, ligatures, tissue fixation devices. Removal of endometrial ablation system catheters form scope. Addition of 'Ethicon a division of Johnson and Johnson Medical Limited' as a significant subcontractor.
03 November 2014	8226942	Certificate Renewal. Extension to scope to add surgical support tapes (non-absorbable, sterile). Addition of Johnson and Johnson Medical Limited, EH54 7AT as significant subcontractor. Removal of 'Johnson & Johnson Medical Limited, EH54 0AB' and 'Ethicon a division of Johnson and Johnson Medical Limited, EH54 0AB' as significant subcontractors. Update to certificate format. Administrative update to OEM information.
11 March 2015	8284900	Addition of Surgical Bone Wax (sterile) to scope.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2019-11-07**

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USA

Date	Reference Number	Action
29 June 2017	8595339	Certificate template update for virtual manufacturer. Extension to scope to include associated applicators, bolsters, beads and collars, clips, and pledges (sterile) for sutures. Addition of the following significant subcontractors: Ethicon Endo-Surgery, Inc. (Gamma Sterilization), Ethicon Inc, Athens (manufacture), Ethicon Inc, San Angelo (manufacture, sterilization), Ethicon, Inc., Somerville (Design, regulatory compliance), Ethicon Inc., Cornelia (manufacturer), Ethicon Inc., Juarez (manufacture, packaging), Johnson & Johnson do Brasil Indústria (manufacture, packaging, sterilization), Johnson & Johnson Medical (China) Ltd. (manufacture), Isomedix Operations Inc, Whippany (sterilization), Isomedix Operations Inc, Texas, (sterilization) and Isomedix (Puerto Rico) Inc.), Vega Alta (sterilization).

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
05 December 2017	8800949	Addition of Edno-Surgery, Inc. Ohio as significant subcontractor for Design. Addition of Suture Cartridges to scope. Addition of Johnson & Johnson MEDICAL GmbH as EU Representative. Addition of Sterigenics US LLC as significant subcontractor for ETO Sterilization. Addition of Ethicon LLC San Lorenzo as significant subcontractor for Manufacture. Correction of street number for Sterigenics, Charlotte.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
22 February 2019	7781391	Administrative Subcontractor Service wording update for: '*Sterilization*' to '*Gamma Sterilization*' for Isomedix (Puerto Rico), Inc., KM 1.7 Barrio Sabana Hoyos, Vega Alta. '*Sterilization*' to '*ETO Sterilization*' for Isomedix Operations, Inc., 1435 Isomedix Place, El Paso. '*Sterilization*' to '*Gamma Sterilization*' for Isomedix Operations, Inc., 9 Apollo Drive, New Jersey. '*Sterilization*' to '*Gamma Sterilization*' and '*ETO Sterilization*' for Johnson & Johnson do Brasil Indústria e Comércio de Productos Para Saúde Ltda., São Paulo. Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2019-11-07**
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Date	Reference Number	Action
07 November 2019	3068351	Removal of "Suture Cartridges (sterile)" from certificate scope. Addition of crucial medicinal substance supplier, BASFSE. Removal of subcontractor for design, Ethicon Endo-Surgery, Inc. Change in name of subcontract sterilizer, Isomedix (Puerto Rico), Inc. to Steris Isomedix Puerto Rico LLC. Addition of "manufacture" to the services supplied for Johnson & Johnson Medical GmbH. Administrative update to the certificate supplementary page to include device table. Certificate renewal.

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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		
06 May 2022	3676171	Acknowledgement of typographical error in device table for the VICRYL Rapide Suture reference number under the Intended purpose of IFU section. CE 575854 is listed; however, CE 574854 is the correct certificate number.
17 June 2022	3346852	Addition of Nypro Healthcare Baja Inc. as a subcontractor for Radiation (Gamma Sterilization). Removal of Johnson & Johnson Medical Ltd (Kirkton) as EU representative. Address change for Ethicon, Inc. from Route 22 West, P.O. Box 151, Somerville, New Jersey 08876-0151, USA to 1000 Route 202, Raritan, New Jersey 08869, USA.

Inspiring trust for a more resilient world.

17 June 2022

Ethicon, LLC
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

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 555605	93/42/EEC Annex II excluding Section 4	3346852	Addition of Nypro Healthcare Baja Inc. as a subcontractor for Radiation (Gamma Sterilization). Removal of Johnson & Johnson Medical Ltd (Kirkton) as EU representative. Address change for Ethicon, Inc. from Route 22 West, P.O. Box 151, Somerville, New Jersey 08876-0151, USA to 1000 Route 202, Raritan, New Jersey 08869, USA.

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,

Graeme Tunbridge
Senior Vice President, Medical Devices