By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 549314**

Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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: **2009-07-10** Date: **2021-04-30** Expiry Date: **2024-05-26**

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Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
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Supplementary Product Information for Quality Management System Certificate

Number	Device Name	Intended purpose per IFU
Class III		
---	SURGICEL/TABOTAMP Absorbable Hemostat	See CE 549332
---	TEMPORARY CARDIAC PACING WIRE	See CE 549334
---	MERSILENE Suture and MERSUTURE Suture	See CE 549326
---	ETHIBOND EXCEL Suture	See CE 549316
---	PROLENE Suture	See CE 549330
---	ETHILON Suture	See CE 549317
---	PRONOVA Sutures	See CE 549331
---	MERSILK and PERMA-HAND Suture	See CE 549328
---	NUROLON Suture	See CE 549329

First Issued: **2009-07-10** Date: **2021-04-30** 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.
60842	GYNECARE GYNEMESH PS PROLENE Soft Mesh	GYNECARE GYNEMESH is indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted.
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.

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Number	Device Name	Intended purpose per IFU
Class IIb		
60300	PROLENE Mesh	PROLENE Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.

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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:

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Date:	**2021-04-30**
Issued To:	**Ethicon, LLC** **Highway 183 Km 8.3** **San Lorenzo** **Puerto Rico** **00754** **USA**

Subcontractor:	**Service(s) supplied**
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	**ETO Sterilization** **Manufacture**
Ethicon Inc 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Ethicon, Inc. P.O. Box 151 Route 22 West Somerville New Jersey 08876-0151 USA	**Design** **Regulatory Compliance**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Radiation (Gamma Sterilization)**
Janssen Pharmaceutical, Inc. 1440 Olympic Drive Athens Georgia 30601 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Johnson & Johnson do Brasil Indústria e Comércio de Prodcutos Para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo Brasil	**ETO Sterilization** **Gamma Irradiation** **Manufacture** **Radiation (Gamma Sterilization)**
Johnson & Johnson Medical (China) Ltd. No 75 Nangu Zhi Road, Minhang 200245 Shanghai China	**Manufacture**
Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
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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Subcontractor:	**Service(s) supplied**
The Secant Group, LLC 195 O'Neill Drive Quakertown Pennsylvania 18951 USA	**Manufacture**
The Secant Group, LLC 430 South 8th Street Perkasie Pennsylvania 18944 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
10 July 2009	7360600	First Issue.
13 October 2009	7437060	Addition of ETHILON Blue polyamide sutures to the supplementary page product list.
20 August 2012	7843532	Update to new certificate format. Administrative change to scope product families for clarity. Addition of Temporary Cardiac Pacing Wires (Sterile) to scope. Addition of EU representatives. Addition of Tissue Sealants for Internal Surgical Applications (Sterile) to scope.
14 May 2013	7983862	Addition of 'Pelvic organ prolapse urogynaecological surgical mesh (sterile)' and the addition of 'Johnson & Johnson Medical Ltd, EH54 7AT' as EU representative.

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Date	Reference Number	Action
02 June 2014	8149277 8124079	Administrative update to scope to match OEM cert. Removal of Ethicon a division of Johnson and Johnson Medical Limited & Johnson and Johnson Medical Limited. PO Box 1988 subcontractors. Change of name for subcontractor Johnson & Johnson Medical Limited to Johnson & Johnson Medical Ltd. Addition of Johnson & Johnson Medical GmbH as EU rep. Certificate renewal. Expiry date realigned with that of OEM.
11 March 2015	8284899	Removal of surgical bonewax from scope.

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Date	Reference Number	Action
29 June 2017	8595347	Certificate template update for virtual manufacturer. Addition of the following significant subcontractors: Ethicon Endo-Surgery, Inc. (Gamma Sterilization). Ethicon Inc 1420 Olympic Drive (manufacture), Ethicon Inc. 3348 Pulliam Street (manufacture, sterilization), Ethicon, Inc., Somerville (Design, regulatory compliance), Ethicon Inc., Cornelia (manufacturer), Johnson & Johnson do Brasil Indústria (manufacture, sterilization), Johnson & Johnson Medical (China) Ltd. (manufacture), The Secant Group, LLC (manufacture), Sterigenics US, LLC, Charlotte (sterilization), Sterigenics US, LLC, New York (sterilization), Isomedix Operations Inc, Whippany (sterilization), Isomedix (Puerto Rico) Inc., Vega Alta (sterilization) and Janssen Pharmaceutical, Inc. (manufacture).
05 December 2017	8803021	Removal of Tissue Sealants for Internal Surgical Applications. Correction of street address for The Secant Group, Perkasie and correction of street number for Sterigenics, Charlotte.

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Date	Reference Number	Action
28 March 2018	8602688	Addition of Packaging and EO Sterilization activities to the Johnson & Johnson Medical Ltd, Livingston site.
27 June 2018	8895435	Removal of Pelvic Organ Prolapse Urogynaecological Surgical Mesh (Sterile) and Surgical Meshes (absorbable, sterile) from the certificate scope. Addition of The Secant Group, LLC (Quakertown, PA) for provision of subcontract manufacture services. Administrative updates to define the sterilization type of service supplied for subcontractors Ethicon, Inc. (San Angelo, TX), Isomedix (Puerto Rico), Inc., Isomedix Operations, Inc. (Whippany, NJ), Johnson & Johnson do Brasil Indústria e Comércio de Productos Para Saúde Ltda., and Sterigenics US, LLC (Queensbury, NY). Address change for Sterigencis US, LLC from Glen Falls, NY to Queensbury, NY. Certificate Renewal.
22 February 2019	7781320	Traceable to NB 0086.

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Date	Reference Number	Action
30 April 2021	3110268	Remove Johnson and Johnson Medical Ltd located on Simpson Parkway, Kirkton Campus, Livingston, Scotland EH54 74T, United Kingdom. Removal of Ethicon Endo-Surgery Inc. Administrative update to add supplementary tables. Administrative change to subcontractor name from Isomedix (Puerto Rico), Inc to STERIS Isomedix Puerto Rico LLC. Certificate Renewal.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 July 2022	3675340	Scope reduction to remove Temporary Cardiac Pacing Wire from the scope of certification

Inspiring trust for a more resilient world.

18 July 2022

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
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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 549314	93/42/EEC Annex II excluding Section 4	3675340	Scope reduction to remove Temporary Cardiac Pacing Wire from the scope of certification. Device is removed from the device schedule

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