

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**

...making excellence a habit.™

Page 1 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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**

...making excellence a habit.™

Page 2 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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.

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

...making excellence a habit.™

Page 3 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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.

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

...making excellence a habit.™

Page 4 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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 549314**
 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

...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 549314**
 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.
 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

...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 549314**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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
 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

...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 549314**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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)

...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 549314**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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
 Perkasio
 Pennsylvania
 18944
 USA

Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 549314**
Date: **2021-04-30**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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.

...making excellence a habit.™

Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 549314**
Date: **2021-04-30**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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.

...making excellence a habit.™

Page 2 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 549314**
Date: **2021-04-30**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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, Perkasio and correction of street number for Sterigenics, Charlotte.

...making excellence a habit.™

Page 3 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 549314**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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 Produtos Para Saúde Ltda., and Sterigenics US, LLC (Queensbury, NY). Address change for Sterigenics US, LLC from Glen Falls, NY to Queensbury, NY. Certificate Renewal.
22 February 2019	7781320	Traceable to NB 0086.

...making excellence a habit.™

Page 4 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 549314**
Date: **2021-04-30**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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

...making excellence a habit.™

Page 5 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

18 July 2022

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

To whom it may concern,

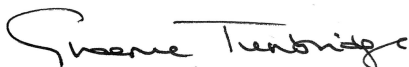
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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 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