EC Design-Examination Certificate

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

No. **CE 549317**

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

In respect of:

ETHILON™ Polyamide 6 or Polyamide 6, 6 Sterile Synthetic Non-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: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 549317

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
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Ethilon Polyamide 6 or Polyamide 6, 6 Sterile Synthetic Non-Absorbable Suture 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 Gauge Size	0.1-5.0 (Metric)
Suture Length	5 cm - 200 cm
Suture Dyed / Undyed	Dyed / Undyed
Suture Color (if dyed)	Black / Green
Suture Coated / Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/ No)	No
Triclosan Levels (ug/m)	N/A
Accessories to suture type	Lead Seal and Surgical Bolster, Retention Tubing
Needled / Non-Needled	Needled / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, 455 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver/ Black
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm

First Issued: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 549317

Issued To:

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

Certificate History

Date	Reference Number	Action
16 June 2009	7360602	First issue.
20 August 2012	10135926	Update to new certificate format. Administrative change to supplementary page for clarity.
08 July 2013	10142695	Suture range restricted to current product range and updated to align with OEM CE 01589. Clarification changes. Administrative correction to trademark symbols in scope and administrative addition of supplementary information category 'Suture Needled/Non-needled'.
30 May 2014	10147239	Certificate renewal. Administrative update to supplementary page information. Administrative update to scope. Expiry date realigned with that of the OEM.

First Issued: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

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Supplementary Information to CE 549317

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
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Date	Reference Number	Action
04 December 2015	10153616	Addition of needle coating types CERBERUS & MULTIPASS. Addition of Needle Master File.
19 January 2016	10158430	Add global product codes and updates to labelling and IFU (San Lorenzo and Guaynabo only). Addition of MULTIPASS needle coating type. Addition of Lead Seal and Surgical Bolster. Administrative update to scope.
20 April 2016	10158891	Change in labelling for the removal of special storage conditions and update to the IFU content. Administrative modifications.
06 June 2016	10147241	Review of automated winding machinery, removal of pins in winding machines, change to supplier of the polymer resin used for the suture and use of Zipper III trays. Administrative change to certificate format.
05 July 2016	10162034	New global product codes implemented at San Lorenzo and Ciudad Juarez (VANTAGE 2). Administrative update to supplementary page content.

First Issued: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 549317

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
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USA

Date	Reference Number	Action
26 October 2016	10164519	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing (for size USP 3-0, Metric 2 only).
02 December 2016	10166518	New global product codes implemented at San Lorenzo and Ciudad Juarez (VANTAGE 3). Administrative update to supplementary page content.
21 November 2017	8748900	New global product codes implemented at San Lorenzo (Vantage 4). Addition of ETHILON Green. Administrative update to supplementary page content.
22 February 2019	7781320	Traceable to NB 0086.
10 June 2019	9714787	Renewal.

First Issued: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 549317

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
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Date	Reference Number	Action
28 February 2020	9690294	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.
	9689454	New global product codes implemented at San Lorenzo (Project VANTAGE).
03 April 2020	9690712 3105453	Addition of the ETHLION™ Suture sizes USP 2-0 (Metric 3.0) and USP 4-0 (Metric 1.5) manufactured at the Ethicon, Inc. Athens, Georgia manufacturing facility. Addition of manufacture for micro needles (sizes 2.4 mil to 4.8 mil) at the Johnson & Johnson do Brasil (São José dos Campos, Brasil) manufacturing facility.
Current	3249430	Implementation of the Flexible Automatic Swage (FAS) Stake Swage Process at Ethicon, LLC, San Lorenzo, Puerto Rico, USA.

First Issued: **2009-06-16** Date: **2021-03-29** Expiry Date: **2024-05-26**

By Royal Charter

Supplementary Information to CE 549317 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 15 November 2021

Changes Approved:

Date	Reference Number	Action
15 November 2021	3261223	Amended - Implementation of two new overwrapping machines at Ethicon, LLC, San Lorenzo. Modification of the format of the cartons and IFUs used at this facility to accommodate the new overwrapping machines.

Inspiring trust for a more resilient world.

15 November 2021

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 549317	93/42/EEC Annex II Section 4	3261223	Amended - Implementation of two new overwrapping machines at Ethicon, LLC, San Lorenzo. Modification of the format of the cartons and IFUs used at this facility to accommodate the new overwrapping machines.

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

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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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
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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**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
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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.

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

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 549314

Issued To:

Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
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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.

First Issued: **2009-07-10** 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 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**

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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

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**

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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

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 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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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)**

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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

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 Perkasie Pennsylvania 18944 USA	**Manufacture**

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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.

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
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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.

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

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
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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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 549314**

Date: **2021-04-30**

Issued To: **Ethicon, LLC**
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Date	Reference Number	Action
Current	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.