

EC Certificate - Full Quality Assurance System

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

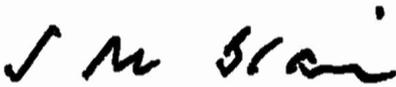
No. CE 549314
Issued To: Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2018-06-27**

Expiry Date: **2023-07-01**

...making excellence a habit.™

Page 1 of 2

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**

Hemostasis Devices (Absorbable & Non-absorbable, Sterile)
Surgical Meshes (Non-Absorbable, Sterile)
Surgical Support Tapes (Non-Absorbable, Sterile)
Sutures and Ligatures (Needled & Non-needled, Absorbable & Non-absorbable, Synthetic (including Stainless Steel) & Non-synthetic, Non-medicated) and associated accessories. (Sterile)
Temporary Cardiac Pacing Wires (Sterile)

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

Date: **2018-06-27**

Expiry Date: **2023-07-01**

...making excellence a habit.™

Page 2 of 2

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: **2018-06-27**
Issued To: **Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA**

Subcontractor:

Service(s) supplied

Ethicon Endo-Surgery, Inc.
3801 University Boulevard SE
Albuquerque, NM 87106
USA

Gamma Sterilization

Ethicon Inc
1420 Olympic Drive
Athens
Georgia
30601
USA

Manufacture

Ethicon Inc
3348 Pulliam Street
San Angelo
Texas
76905
USA

**ETO Sterilization
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: **2018-06-27**
Issued To: **Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA**

Subcontractor:

Service(s) supplied

Ethicon Inc
655 Ethicon Circle
Cornelia
Georgia
30531
USA

Manufacture

Ethicon, Inc.
P.O. Box 151
Route 22 West
Somerville
New Jersey
08876-0151
USA

**Design
Regulatory Compliance**

Isomedix (Puerto Rico), Inc.
State Road 690
KM 1.7 Barrio Sabana Hoyos
Vega Alta
00692
Puerto Rico

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: **2018-06-27**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	Gamma Sterilization
Janssen Pharmaceutical, Inc. 1440 Olympic Drive Athens Georgia 30601 USA	Manufacture
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 Gamma Sterilization 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: **2018-06-27**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Subcontractor:	Service(s) supplied
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
Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston Scotland EH54 7AT United Kingdom	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: **2018-06-27**
Issued To: **Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA**

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization
The Secant Group, LLC 195 O'Neill Drive Quakertown Pennsylvania 18951 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: **2018-06-27**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Subcontractor:

Service(s) supplied

The Secant Group, LLC
430 South 8th Street
Perkasie
Pennsylvania
18944
USA

Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 549314**
 Date: **2018-06-27**
 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 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 Certificate History

Certificate No: **CE 549314**
 Date: **2018-06-27**
 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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 549314**
 Date: **2018-06-27**
 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 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

Certificate History

Certificate No: **CE 549314**
 Date: **2018-06-27**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

28 March 2018	8602688	Addition of Packaging and EO Sterilization activities to the Johnson & Johnson Medical Ltd, Livingston site.
Current	8895435	<p>Removal of Pelvic Organ Prolapse Urogynaecological Surgical Mesh (Sterile) and Surgical Meshes (absorbable, sterile) from the certificate scope.</p> <p>Addition of The Secant Group, LLC (Quakertown, PA) for provision of subcontract manufacture services.</p> <p>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).</p> <p>Address change for Sterigenics US, LLC from Glen Falls, NY to Queensbury, NY.</p> <p>Certificate Renewal.</p>