

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 549311****Issued To:**

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

In respect of:

**The manufacture of Tissue Sealants and adhesives for topical surgical applications (sterile),
Sutures (sterile, synthetic, non-absorbable) Endoscopic Instruments (sterile).**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2009-06-05**

Date: **2021-04-30**

Expiry Date: **2024-05-26**

...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 - Production Quality Assurance

Supplementary Information to CE 549311

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0303	DERMABOND Topical Skin Adhesive	---
MD 0303	DERMABOND PRINEO Skin Closure System	---
MD 0302	Blue ETHILON Suture	---
MD 0106	Surgicel Endoscopic Applicator	---

First Issued: **2009-06-05**Date: **2021-04-30**Expiry Date: **2024-05-26**

...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.

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 - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 549311**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Subcontractor:	Service(s) supplied
Alltrista Plastics LLC 20 Setar Way Reedsville Pennsylvania 17084 USA	Manufacture
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

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 549311**
 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 Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	EU Representative
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

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 549311**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Subcontractor:

Service(s) supplied

Steris Isomedix Puerto Rico LLC
 State Road 690
 KM 1.7 Barrio Sabana Hoyos
 Vega Alta
 00692
 Puerto Rico

Radiation (Gamma Sterilization)

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 549311**
Date: **2021-04-30**
Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Date	Reference Number	Action
05 June 2009	7360599	First issue.
28 January 2010	7479490	Extension to scope to include "Sterile and Non-Sterile Medical Adhesives for Topical Applications".
20 August 2012	7843533	Update to new certificate format. Administrative change to scope product families for clarity. Addition of Sutures (sterile, synthetic, non-absorbable). Addition of EU representatives.
02 June 2014	8124079	Certificate renewal. Expiry date realigned with that of the OEM.
25 April 2016	8332735	Removal of polypropylene buttons from scope. Update of OEM page to reflect current certificate.

...making excellence a habit.™

Page 1 of 3

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 - Production Quality Assurance

Certificate History

Certificate No: **CE 549311**
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	8595344	Certificate template update for virtual manufacturer. Administrative change to scope to include Endoscopic Instruments (Sterile). Addition of significant subcontractors: Sterigenics US, LLC (New York), Sterigenics US, LLC (North Carolina), Ethicon Inc. (Georgia), Isomedix (Puerto Rico), Inc., Ethicon Inc. (New Jersey), Ethicon Endo-Surgery Inc. and Jarden Plastics Solutions (Pennsylvania) for sterilization, regulatory compliance and manufacture activities.
05 December 2017	8845786	Addition of Johnson & Johnson MEDICAL GmbH as EU Representative.

...making excellence a habit.™

Page 2 of 3

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 - Production Quality Assurance

Certificate History

Certificate No: **CE 549311**
 Date: **2021-04-30**
 Issued To: **Ethicon, LLC**
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Date	Reference Number	Action
27 June 2018	8895434	Administrative updates to define the sterilization type for subcontractors Ethicon Endo-Surgery, Inc., Isomedix (Puerto Rico), Inc., Sterigenics US, LLC (Charlotte, NC), and Sterigenics US, LLC (Queensbury, NY). Addition of design to the service supplied for Ethicon, Inc. (Somerville, NJ). Address update from Glen Falls, New York to Queensbury, New York for subcontract sterilizer, Sterigenics US, LLC. Certificate Renewal.
22 February 2019	7781320	Traceable to NB 0086.
Current	3110322	Remove Johnson and Johnson Medical Ltd located on Simpson Parkway, Kirkton Campus, Livingston, Scotland EH54 74T, United Kingdom Removal of Ethicon Endo-Surgery Inc. Change of name for subcontractor "Jarden Plastic Solutions" to "Alltrista Plastics LLC." Addition of supplementary tables Administrative change to subcontractor name from Isomedix (Puerto Rico), Inc to STERIS Isomedix Puerto Rico LLC Certificate Renewal.

...making excellence a habit.™

Page 3 of 3

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.