

EC Certificate - Production Quality Assurance

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

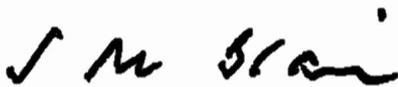
No. CE 549311
Issued To: Ethicon, LLC
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2009-06-05**Date: **2017-06-29**Expiry Date: **2018-07-01**

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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.

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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: **2017-06-29**
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	Sterilization
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	Regulatory Compliance

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USA**

Subcontractor:	Service(s) supplied
Isomedix (Puerto Rico), Inc. State Road 690 KM1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	Sterilization
Jarden Plastic Solutions 20 Setar Way Reedsville Pennsylvania 17084 USA	Manufacture
Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	EU Representative

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Subcontractor:

Service(s) supplied

Sterigenics US, LLC
10821 Withers Cove Park Drive
Charlotte
NC 28278
USA

Sterilization

Sterigenics US, LLC
84 Park Road
Glen Falls
New York
12804
USA

Sterilization

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EC Certificate - Production Quality Assurance Certificate History

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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.

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Date	Reference Number	Action
Current	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.

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