By Royal Charter

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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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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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.