

EC Certificate - Full Quality Assurance System

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

No.

CE 555605

Issued To:

**Ethicon, LLC
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA**


In respect of:

The design, development and manufacture of:

- **Sutures and ligatures (needled and non-needled, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic, medicated and non-medicated) and associated applicators, bolsters, beads and collars, clips, and pledges (sterile)**
- **Tissue Fixation Devices (absorbable and non-absorbable, sterile)**
- **Surgical Bone Wax (sterile)**
- **Surgical Support Tapes (non-absorbable, sterile)**

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: **2009-11-13**

Date: **2017-06-29**

Expiry Date: **2019-11-12**

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Page 1 of 1

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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List of Significant Subcontractors

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

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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	Manufacture Sterilization

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Subcontractor:**Service(s) supplied**

Ethicon Inc
655 Ethicon Circle
Cornelia
Georgia
30531
USA

Manufacture

Ethicon, Inc.
Calle Durango No. 2751
Lote Bravo
Ciudad Juarez
Chihuahua
C.P. 32575
Mexico

**Manufacture
Packaging**

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

**Design
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
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	Sterilization
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	Sterilization

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Subcontractor:	Service(s) supplied
Johnson & Johnson do Brasil Indústria e Comércio de Produtos Para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	Manufacture Packaging Sterilization
Johnson & Johnson Medical (China) Ltd. No 75 Nangu Zhi Road, Minhang 200245 Shanghai China	Manufacture
Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	EU Representative

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Certificate History

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Date	Reference Number	Action
13 November 2009	7449449	First issue.
23 May 2012	7829754	Update of certificate format. Administrative change to scope language for sutures, ligatures, tissue fixation devices. Removal of endometrial ablation system catheters form scope. Addition of 'Ethicon a division of Johnson and Johnson Medical Limited' as a significant subcontractor.
03 November 2014	8226942	Certificate Renewal. Extension to scope to add surgical support tapes (non-absorbable, sterile). Addition of Johnson and Johnson Medical Limited, EH54 7AT as significant subcontractor. Removal of 'Johnson & Johnson Medical Limited, EH54 0AB' and 'Ethicon a division of Johnson and Johnson Medical Limited, EH54 0AB' as significant subcontractors. Update to certificate format. Administrative update to OEM information.
11 March 2015	8284900	Addition of Surgical Bone Wax (sterile) to scope.

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Page 1 of 2

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Date	Reference Number	Action
Current	8595339	<p>Certificate template update for virtual manufacturer.</p> <p>Extension to scope to include associated applicators, bolsters, beads and collars, clips, and pledges (sterile) for sutures.</p> <p>Addition of the following significant subcontractors:</p> <p>Ethicon Endo-Surgery, Inc. (Gamma Sterilization), Ethicon Inc, Athens (manufacture), Ethicon Inc, San Angelo (manufacture, sterilization), Ethicon, Inc., Somerville (Design, regulatory compliance), Ethicon Inc., Cornelia (manufacturer), Ethicon Inc., Juarez (manufacture, packaging), Johnson & Johnson do Brasil Indústria (manufacture, packaging, sterilization), Johnson & Johnson Medical (China) Ltd. (manufacture), Isomedix Operations Inc, Whippany (sterilization), Isomedix Operations Inc, Texas, (sterilization) and Isomedix (Puerto Rico) Inc.), Vega Alta (sterilization).</p>

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Page 2 of 2

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