bsi.

By Royal Charter

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 pledgets (sterile)
- Tissue Fixation Devices (absorbable and non-absorbable, sterile)
- Surgical Bone Wax (sterile)
- Surgical Support Tapes (non-absorbable, sterile)
- Suture Cartridges (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: **2017-12-05** Expiry Date: **2019-11-12**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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Supplementary Information to CE 555605

Issued To:

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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 Endo-Surgery, Inc. 4545 Creek Road Cincinnati Ohio 45242 USA	**Design**
Ethicon Inc 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	**Manufacture** **Sterilization**
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**

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Subcontractor:	**Service(s) supplied**
Ethicon, Inc. P.O. Box 151 Route 22 West Somerville New Jersey 08876-0151 USA	**Design** **Regulatory Compliance**
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico USA	**Manufacture**
Isomedix (Puerto Rico), Inc. State Road 690 KM1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	**Sterilization**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	**Sterilization**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Sterilization**
Johnson & Johnson do Brasil Indústria e Comércio de Productos Para Saúde Ltda. Rod. Presiodente Dutra - KM 154 São José dos Campos São Paulo 12240-908 Brasil	**Manufacture** **Packaging** **Sterilization**

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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 EH54 7AT United Kingdom	**EU Representative**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**

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