

EC Certificate - Production Quality Assurance

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

No.**CE 555607**

Issued To:

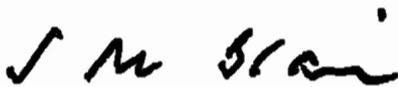
**Ethicon, LLC
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA**

In respect of:

See certificate scope page.

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: **2009-11-12**Date: **2017-12-05**Expiry Date: **2019-11-11****...making excellence a habit.™**

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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.

Certificate No: CE 555607

Certificate Scope:

The manufacture of:

Elastic tubing to secure veins, arteries, nerves and ureters (Sterile)

Sutures (Sterile, Synthetic, Non-Absorbable)

Surgical support tapes (Non-Absorbable, Sterile)

Those aspects of manufacture related to securing and maintaining sterility of:

Umbilical Cord Tape (Sterile)

First Issued: **2009-11-12**Date: **2017-12-05**Expiry Date: **2019-11-11**

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Supplementary Information to CE 555607

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First Issued: **2009-11-12**

Date: **2017-12-05**

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

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Page 3 of 3

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List of Significant Subcontractors

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

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Date: **2017-12-05**
Issued To: **Ethicon, LLC**
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

Subcontractor:	Service(s) supplied
Ethicon Endo-Surgery, Inc. 3801 University Boulevard SE Albuquerque, NM 87106 USA	Sterilization
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	Sterilization
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	Manufacture

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Puerto Rico
00969
USA

Subcontractor:	Service(s) supplied
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	Regulatory Compliance
Isomedix (Puerto Rico), Inc. State Road 690 KM1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico	Sterilization

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USA

Subcontractor:

Service(s) supplied

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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