

EC Certificate - Production Quality Assurance

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

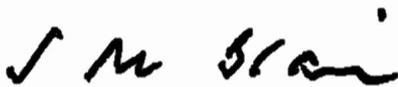
No. CE 555607
Issued To: Ethicon, LLC
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

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: **2017-06-29**Expiry Date: **2019-11-11**

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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: **2017-06-29**Expiry Date: **2019-11-11**

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List of Significant Subcontractors

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

Certificate No: **CE 555607**
Date: **2017-06-29**
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475 C Street
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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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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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Subcontractor:

Service(s) supplied

Johnson & Johnson Medical Ltd
Simpson Parkway
Kirkton Campus
Livingston
EH54 7AT
United Kingdom

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
12 November 2009	7449450	First issue.
31 July 2012	7843535	Administrative change to clarify scope language. Update to new certificate format. Addition of EU representatives Ethicon and Johnson and Johnson Medical Ltd.
23 May 2013	7945177	The addition of 'Elastic tubing to secure veins, arteries, nerves and ureters (Sterile)', 'Sutures (Sterile, Synthetic, Non-Absorbable)', 'Surgical Support Tapes (Non-Absorbable, Sterile)', and 'Fixation Clips (Sterile)' to scope.
20 December 2013	8035854	Administrative change to address of certificate and OEM address. The removal of 'Ethicon a division of Johnson and Johnson Medical Limited, EH54 0AB' and 'Johnson and Johnson Medical Limited, EH54 0AB' as significant subcontractors. The addition of significant subcontractor 'Johnson and Johnson Medical Limited, EH54 7AT' as EU Representative.
03 November 2014	8226967	Certificate renewal.

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Date	Reference Number	Action
25 April 2016	8332735	Change for Umbilical Cord tape from full Annex V coverage to limited coverage. Removal of fixations clips and retention suture bridges from scope. Update of OEM page to reflect current certificate.
Current	8595341	Certificate template update for virtual manufacturer. Addition of significant subcontractors: Ethicon Inc. (Georgia), Isomedix (Puerto Rico) Inc., Ethicon Inc. (New Jersey), Ethicon Endo-Surgery Inc., Ethicon Inc. (Chihuahua), Ethicon Inc. (Texas) for sterilization, manufacture, regulatory compliance and packaging activities.