

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), Tissue Fixation Devices (absorbable and non-absorbable, sterile), Surgical Bone Wax (sterile) and 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):



Pietro Foschi - Strategic Delivery Director

First Issued: **13 November 2009**

Date: **11 March 2015**

Expiry Date: **12 November 2019**

...making excellence a habit.™

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 555605
Date: 11 March 2015
Issued To: Ethicon, LLC
 475 C Street
 Los Frailes Industrial Park
 Suite 401
 Guaynabo
 Puerto Rico
 00969
 USA

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.

...making excellence a habit.™

Page 1 of 2

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 555605**
 Date: **11 March 2015**
 Issued To: **Ethicon, LLC**
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

Date	Reference Number	Action
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.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 555605

Issued To:

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

This certificate is issued under the OWN BRAND LABELLING process

OEM Information

Name	Ethicon, Inc. Also trading as Ethicon Women's Health & Urology, a Division of Ethicon, Inc.
Address	Route 22 West, P.O. Box 151 Somerville, New Jersey 08876-0151 USA
Notified Body	BSI
Certificate No.	CE 00384

First Issued: **13 November 2009**

Date: **11 March 2015**

Expiry Date: **12 November 2019**

...making excellence a habit.™

Page 1 of 3

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.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 555605

Issued To:

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

<p>Scope</p>	<p>Design, development and manufacture of:</p> <ul style="list-style-type: none"> Absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (Sterile) Endometrial Ablation Systems (Sterile & Non-Sterile) Haemostasis Device (Absorbable & Non-absorbable, Sterile) Hysteroscopic Bi-polar Electrosurgical Instruments, Systems and Associated Electrodes (Sterile & Non- Sterile) Laparoscopic Morcellator Instruments (Sterile) Motor Drives for Surgical Instruments (Non-Sterile) Pelvic organ prolapse urogynaecological surgical mesh (Sterile) Pledgets (Sterile) Surgical Bone Wax (Sterile) Surgical Meshes (Absorbable and Non-Absorbable, Sterile) Surgical Support Tapes (Non Absorbable, Sterile) Sutures and ligatures (Needled and non-needed, absorbable and non-absorbable, synthetic (including stainless steel) and non-synthetic, medicated and non-medicated) and associated accessories (Sterile)
---------------------	--

First Issued: **13 November 2009**

Date: **11 March 2015**

Expiry Date: **12 November 2019**

...making excellence a habit.™

Page 2 of 3

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.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 555605

Issued To:

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

	Temporary cardiac Pacing Wires (Sterile) Tissue Fixation devices (Absorbable, Sterile) Tissue Sealants for Internal Surgical Applications (Sterile) Urinary Stress Incontinence Devices (Sterile & Non- Sterile) Wound Dressings (Antimicrobial, Sterile)
Issue / Reissue Date	09 December 1994 / 19 August 2014
Route to Conformity	Directive 93/42/EEC, Annex II, Section 3.2

The validity of this OBL certificate is conditional on the continuing validity of the Original Equipment Manufacturer's certification under the Medical Device Directive and the maintenance of the relevant control exercised by the Own Brand Labeller.

First Issued: **13 November 2009**

Date: **11 March 2015**

Expiry Date: **12 November 2019**

...making excellence a habit.™

Page 3 of 3

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.

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No: **CE 555605**
Date: **11 March 2015**
Issued To: **Ethicon, LLC**
475 C Street
Los Frailes Industrial Park
Suite 401
Guaynabo
Puerto Rico
00969
USA

Subcontractor:

Service(s) supplied

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

EU Representative

...making excellence a habit.™