

EC Certificate - Full Quality Assurance System

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

No.**CE 00384****Issued To:**

Ethicon, Inc.
Also Trading as Ethicon Women's Health
& Urology, a Division of Ethicon, Inc.
PO Box 151
Route 22 West
Somerville
New Jersey
08876-0151
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 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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 December 1994**

Date: **13 July 2016**

Expiry Date: **01 July 2018**

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Certificate No: CE 00384

Certificate Scope:

Design, development and manufacture of:

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)

Pelvic organ prolapse urogynaecological surgical mesh (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)

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)

First Issued: **09 December 1994**Date: **13 July 2016**Expiry Date: **01 July 2018**

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List of Significant Subcontractors

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Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Inerior B1, C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tijuana C.P. 22116 Mexico	Manufacture
CEA Medical Manufacturing 1735 Merchants Court Colorado Springs Colorado 80916 USA	Manufacture
Ethicon Endo-Surgery, Inc. 3801 University Boulevard SE Albuquerque, NM 87106 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Ethicon Inc. Avenida de las Torres No. 7125 Ciudad Juarez Chihuahua C.P. 32580 Mexico	Manufacture
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	Manufacture Sterilization
Ethicon Inc 655 Ethicon Circle Cornelia Georgia 30531 USA	Manufacture

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Subcontractor:	Service(s) supplied
Ethicon SARL Puits Godet 20 Neuchâtel 2000 Switzerland	Manufacture
Ethicon, Inc. Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua C.P. 32575 Mexico	Manufacture
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico USA	Manufacture

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Subcontractor:	Service(s) supplied
Gyrus Medical Limited Fortran Road, St Mellons CF3 0LT Cardiff United Kingdom	Design EU Representative Manufacture
Integra LifeSciences Corporation also doing business as Integra NeuroSciences 311 Enterprise Drive Plainsboro New Jersey 08536 USA	Design
Integra NeuroSciences State Road 402, Km 1.2 Añasco Puerto Rico Puerto Rico 00610 USA	Manufacture Packaging

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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
Sterilization

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

Design
EU Representative
Manufacture
Packaging
Sterilization

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Subcontractor:	Service(s) supplied
Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston Scotland EH54 7AT United Kingdom	EU Representative Manufacture Sterilization
J-Pac, LLC 25 Centre Road Somersworth New Hampshire 03878-2927 USA	Manufacture

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Subcontractor:	Service(s) supplied
Manufacturas Zapaliname SA de CV Departamento Gyrys ACMI Nave 28 Carretera Saltillo- Zacatecas KM 4.5 Parque Industrial la Angostura Saltillo Coahuila Mexico Coahuila 25315 Mexico	Manufacture Packaging
Philips Plastics Corporation Phillips Medical New Richmond Short Run 705 Wisconsin Drive New Richmond WI 54017 USA	Manufacture
Plexus Corp 2400 Millbrook Drive Buffalo Grove IL 60089 USA	Manufacture

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Subcontractor:	Service(s) supplied
Plexus Corp 2500 Millbrook Drive Buffalo Grove IL 60089 USA	Manufacture
Secant Medical, Inc. 195 O'Neill Drive Quakertown Pennsylvania 18951 USA	Manufacture
Secant Medical, Inc. 700 Park Avenue Perkasie Pennsylvania 18944 USA	Manufacture

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Subcontractor:	Service(s) supplied
Sterigenics International, Inc. Sterigenics US LLC. 3125 Wichita Court Fort Worth Texas 76140 USA	Sterilization
Sterigenics SAS, part of Sterigenics France 8 Rue Parmentier Rantigny 60290 France	Sterilization
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	Sterilization
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	Sterilization
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 84 Park Road Glens Falls New York 12804 USA	Sterilization
Sterigenics 2311 Lincoln Avenue Hayward CA 94545 USA	Sterilization
STERIS Isomedix Services 1435 Isomedix Place El Paso Texas 79936 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
STERIS Isomedix Services 2072 Southport Road Spartanburg South Carolina 29306 USA	Gamma Sterilization
STERIS Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	Gamma Sterilization
STERIS Isomedix Services State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Synergy Health Däniken AG 4658 Däniken Switzerland	Gamma Sterilization
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	Gamma Sterilization

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Date	Reference Number	Action
9 December 1994		First Issue.
19 November 1996		Change of address details. The operation of Chicago was removed from the list of sub-contractors.
11 November 1997		Scope changed to read:- "For the design, development and manufacture of bipolar electrosurgical scissors, and associated cables and accessories, surgical and endoscopic wound closure devices including sutures, ligatures and associated accessories; surgical mesh devices and tissue sealants/adhesives." Johnson and Johnson Professional, Inc (Raynham); Closure Medical Corporation (Raleigh), EWC, Inc (Pewaukee) and J-PAC Corporation added to the list of sub-contractors.
18 March 1998		"Hemostasis products and electrosurgical bipolar forceps" added to the scope. Kirwan surgical products Inc (Marshfield) added to the list of sub-contractors.

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Date	Reference Number	Action
21 January 2000		Codman and Shurtleff, Inc added to the list of sub-contractors. 5 year renewal.
19 April 2001		Scope re-styled to read: "For the design, development and manufacture of bipolar electrosurgical instruments (coagulation, cutting and dissection devices); surgical and endoscopic wound closure devices including sutures and ligatures (synthetic and non-synthetic types); retention suture bridge; surgical mesh devices, tissue sealants/adhesives; and haemostasis devices" Scope re-styled to read: "For the design, development and manufacture of bipolar electrosurgical instruments (coagulation, cutting and Medsource Technologies (Lacona) added to the list of sub-contractors.
7 April 2003		"Temporary cardiac pacing wires, heart retractors and heart stabilizer systems". added to the scope. Steris Corporation (Northborough and Puerto Rico) added to the list of sub-contractors.

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Date	Reference Number	Action
21 July 2003		"Subcutaneous retractors and dissectors" added to the scope. Medsource Technologies, LLC (Newton) and Ethicon Endo-surgery (Albuquerque) added to the list of sub-contractors.
6 April 2004		Addition of Ion Beam Applications and Steris Isomedix for sterilization and Avail Medical for manufacture.
26 May 2004		Addition of sub-contractors Ethicon Scotland and Johnson & Johnson Medical (China).
14 January 2005		Transferred scope and sub contractors from Certificates CE 73843, CE 75619, cancelling CE 73843, CE 75619, Ethicon Inc (Chihuahua Mexico) added as sub-contract manufacturer and certificate renewal.
29 April 2005		Addition of also trading names, Gynecare, Johnson & Johnson Wound Management, Cardioversions, Ethicon, Inc. to the certificate.
22 December 2005		Filtered CO2 Blowers with Mist added to the scope of the certificate.

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Date	Reference Number	Action
18 January 2006		<p>Addition of Harmac Medical Products, Inc., Buffalo NY 14211, USA Harmac Medical Products Ltd., Ireland and Plexus Corporation, Buffalo IL 60089, USA as manufacture sites to list of significant list of sub-contractors.</p> <p>Addition of Medical lasers and fibres to scope and incorporating the devices previously covered by Heartport QMS certificate CE 92659 into this certificate.</p> <p>Addition of subcontractors, Accellent Endocopy, New Hampshire, USA, Beam One, California, USA, Ion Beam Applications, California, USA, Nutek Corporation, California, USA, as a result of the Heartport transfer in respect of 'Heartport' scope extension.</p>
29 September 2006		The MedTech Group, Inc added as a manufacture subcontractor.
18 December 2006		Addition of Ethicon Inc. Independencia, Chihuahua 32574 for manufacture to the list of significant subcontractors.
11 July 2007		J&J Brazil added as a manufacturing subcontractor.
06 August 2007		Addition of Euromed, Inc. as a manufacturing subcontractor.

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Date	Reference Number	Action
10 August 2007		Addition of Gyrus ACMI as a subcontractor for manufacture and packaging, addition of Sterigenics Texas as a subcontractor for Gamma Sterilization and change of subcontractor name from 'Titan Scan Technologies' to BeamOne LLC'.
26 September 2007		Addition of Steris Isomedix Services Inc facility located in Spartanburg, SC as a sterilization subcontractor.
21 April 2008	7177162	Extension of expiry date from 8 April 2008 to 8 April 2009, as per Jan 2005 renewal.
17 March 2009	7325143	Change of EU Representative.
17 April 2009	7339751	Address modification to reflect divested divisions, scope reduced to remove obsolete products, removed suppliers (Ludlow, Ion Beam Application, Sparton, Plexus, Merit, Edwards Lifesciences, Harmac, Codman and Shurtleff, EWC, Kirwan and some sites for Avail, Euromed and Accellent). Add suppliers (J&J China, Sterigenics, AMS, BOSS, Phillips Plastics). Certificate Renewal.
13 July 2009	7399389	Addition of non-absorbable surgical support tape to scope.

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Date	Reference Number	Action
28 January 2010	7459847	Order of devices in scope changed for clarity. Addition of 'absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose, pelvic floor repair systems and urinary stress incontinence devices'. 'Non-absorbable' added to 'surgical mesh systems'. Addition of Onmex sterile cyano acrylate-based medical adhesive for surgical application. Reformatting of address for clarity. Updated addresses for Gyrus, Ethicon, Livingston, UK, Ethicon LLC, Puerto Rico, Ethicon S.A.S, Isotron Harwell, Ethicon, Inc. Mexico, Isotron, Moray Road, Ethicon, Inc. Texas, USA, Ethicon, Inc. Georgia, USA, Closure Medical, Ethicon, Inc. Lote Bravo, Mexico, J&J Brazil. Addition of EU Rep to J&J Gargrave. Addition of 'Sterilisation' to subcontractor Ethicon Inc, addition of 'Packaging, Sterilisation and EU Representative' to subcontractor Johnson & Johnson MEDICAL GmbH and the addition of Sterigenics SAS for 'Sterilisation' as a subcontractor. Removal of Ethicon, Inc. Salvarcar, Chihuahua, Mexico.
26 May 2010	7523028	Removal of subcontractors 'Degania Medical Devices Pvt Ltd, India' and 'Degania Silicone Limited, Israel'.

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Date	Reference Number	Action
30 November 2010	7611345	The Addition of "Also trading as Closure Medical Corp., a Division of Ethicon Inc." to address. Addition of Sterilisation to activity of subcontractor 'J&J Brazil and addition of Design to activity of subcontractor 'J&J Medical GmbH'.
31 March 2011	7652621	Relocation of full scope to the supplementary information page for improved clarity. Extension to scope to include pledgets and tissue fixation devices. Removal of devices no longer manufactured under the Annex II certificate scope including lasers, retention suture bridges, non-adherent wound dressings and wound packing devices, hydrocolloid wound dressings, hydrogel wound dressings, film wound dressings and fluid management systems. Clarification of scope language. Addition of Sterigenics , Glenfalls as a subcontractor for sterilisation. Removal of Johnson & Johnson Medical Ltd, Gargrave as a subcontractor.

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Date	Reference Number	Action
26 September 2012	7867804	Addition of Surgical Bone Wax (Sterile) to scope. Administrative correct to name of Kirkton site. Correction of EU rep name and address. Removal of Advanced Medical Solutions Limited, Covidien, Euromed & Nutek Corporation as significant subcontractors. Addition of design activity to Integra, Plainsborough. Addition of Integra Lifesciences Corporation, Plexus Corp & Sharp as significant subcontractors. Correction to address for J-Pac, LLC. Change of name for Isotron Didcot and Swindon to Synergy Health Sterilisation UK Ltd. Addition of of Sterigenics SAS as significant subcontractor.
21 March 2013	7948571	Change of name and correction to address for Leoni Studer Hard AG to Synergy Health Däniken AG.

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Date	Reference Number	Action
14 May 2013	7983862	Removal of 'Pelvic Floor Repair Systems (Sterile), Surgical mesh systems, Urodynamic measuring system' and addition of 'Pelvic organ prolapse urogynaecological surgical mesh (sterile)'. Addition of 'Sterilization and EU Representative' to the activities of subcontractor 'Johnson & Johnson Medical Limited, EH54 7AT'.
02 April 2014	8107160	Certificate renewal. Addition of 'Non-Sterile' to Bi-polar Electrosurgical Instruments, Systems and Associated Electrodes (Sterile). Addition of activities design and EU rep to Gyrus Medical. Administrative correction of sterilization method for Synergy Health UK to Gamma. Administrative correction to remove manufacturing and packaging activities from Integra Lifesciences. Administrative correction to remove design from Integra Neurosciences.

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Date	Reference Number	Action
		Removal of significant subcontractors 'Synergy Health Sterilisation UK Ltd, Didcot', 'Beam One, San Diego', 'Beam One, Lima', 'Ethicon a division of Johnson and Johnson Medical Limited, Scotland' and 'Johnson and Johnson Medical Limited, Scotland'. Addition of significant subcontractor 'CEA Medical Manufacturing, Colorado'. Administrative updates to various subcontractor names and addresses.
19 August 2014	8192892	Removal of Also trading as names J&J Wound Management, Gynecare, Closure Medical. Removal of subcontractors Ethicon Inc, Raleigh and Ethicon S.A.S. Administrative update to certificate format.

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00384**
 Date: **13 July 2016**
 Issued To: **Ethicon, Inc.**
Also Trading as Ethicon Women's Health
& Urology, a Division of Ethicon, Inc.
PO Box 151
Route 22 West
Somerville
New Jersey
08876-0151
USA

Date	Reference Number	Action
11 March 2015	8284898	Removal of laproscopic morcellator instruments and motor drives from scope. Removal of Sharp Corporation as subcontractor. Removal of The MedTech Group as subcontractor. Addition of Secant Medical as subcontractor for manufacture.
25 April 2016	8332735	Removal of pledgets from scope. Removal of Accellent Inc as significant subcontractor. Removal of Ethicon LLC Guaynabo as significant subcontractor. Removal of HEI Inc. as significant subcontractor. Removal of Sterigenics SAS as significant subcontractor. Removal of STERIS Isomedix Services Massachusetts and Illinois as significant subcontractor.
13 July 2016	8557375	Addition of Secant Medical (Quakertown) as a significant subcontractor.

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