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.
1000 Route 202
Raritan
New Jersey
08869
USA

In respect of:

Design, development and manufacture of:
Hysteroscopic Bi-polar Electrosurgical Instruments, Systems and Associated Electrodes (Sterile and Non-Sterile)
Surgical Meshes (Absorbable and Non-Absorbable, Sterile)
Sutures and ligatures (Needled and non-needled, absorbable, synthetic and non-medicated) and associated accessories (Sterile)
Wound Dressings (Antimicrobial, 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 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **1994-12-09** Date: **2021-05-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00384

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Number	Device Name	Intended purpose per IFU
Class III		
---	VICRYL Knitted Mesh	See CE 01357
---	BIOPATCH Protective Disk with CHG	See CE 75105
---	VICRYL Suture	See CE 00873
---	PDS II Suture	See CE 00874

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Number	Device Name	Intended purpose per IFU
Class IIb		
See below:	GYNECARE VERSAPOINT Bipolar Electrosurgery System and GYNECARE VERSAPOINT II Bipolar Electrosurgery System	See below
61872	Ball Tip Electrode (5 Up) Twizzle Tip Electrode (5 Up) Spring Tip Electrode (5 Up) GVAP VRS 0° Electrode (5 Up) VRS 2.5mm Angled Loop Electrode (5 Up) VERSAPOINT II 4.0mm Angled Loop Electrode (5 Up)	The GYNECARE VERSAPOINT Hysteroscopic Electrosurgical System Electrodes (5Fr – Ball, Spring and Twizzle) are designed and intended to be operated as a single system. The GYNECARE VERSAPOINT Hysteroscopic System is used in conjunction with continuous-flow hysteroscopes with 5 French or larger working channels for correction of the following pathologies: myomas, polyps, intrauterine adhesions and uterine septa

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Number	Device Name	Intended purpose per IFU
Class IIb		
47487	VERSAPOINT II Connector Cable VERSAPOINT Connector Cable	The GYNECARE VERSAPOINT Hysteroscopic System Connector Cable and GYNECARE VERSAPOINT II Hysteroscopic System Connector Cable are designed to be used with the GYNECARE VERSAPOINT II Generator and Electrodes. The components are designed and intended to be operated as a single system
36336	VERSAPOINT II Footswitch	The GYNECARE VERSAPOINT II Hysteroscopic Footswitch connects to the GYNECARE VERSAPOINT II Hysteroscopic Electrosurgical Generator to activate the electrosurgical system

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Number	Device Name	Intended purpose per IFU
Class IIb		
11490	VERSAPOINT II Generator	The GYNECARE VERSAPOINT II Hysteroscopic Electrosurgical Generator is designed to provide ablation and coagulation by using an amalgamation of VersaPulse (high intensity pulsations for larger electrodes to enable efficient energy delivery) and PK (technology used on original VERSAPOINT generator) technologies. The GYNECARE VERSAPOINT II Hysteroscopic Electrosurgical Generator maintains the compatibility of all VERSAPOINT legacy electrodes, connector cables and footswitches of the VERSAPOINT System.

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Number	Device Name	Intended purpose per IFU
Class IIb		
60300	PROLENE 3D Patch	The PROLENE 3D Patch is indicated for the repair of groin hernia defects that require a reinforcing material to obtain the desired surgical result.
60300	PROLENE Hernia System	The PROLENE Hernia System is indicated for the repair of abdominal wall hernia defects, including inguinal (direct & indirect).

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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:

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Subcontractor:	**Service(s) supplied**
Edwards Lifesciences Technology SARL State Road 402, Km. 1.4 Industrial Park 00610-1577 Anasco Puerto Rico	**ETO Sterilization**
Ethicon Inc 1420 Olympic Drive Athens Georgia 30601 USA	**Manufacture**
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	**ETO Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
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**
Ethicon, LLC Highway 183 Km 8.3 San Lorenzo 00754 Puerto Rico USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Integra LifeScience Corporation Also dba Integra NeuroSciences 1100 Campus Road Princeton New Jersey 08540 USA	**Design**
Integra NeuroSciences State Road 402, Km 1.2 Añasco 00610 Puerto Rico	**Manufacture** **Packaging**
Johnson & Johnson do Brasil Indústria e Comércio de Prodcutos Para Saúde Ltda. Rod. Presidente Dutra - KM 154 São José dos Campos São Paulo Brasil	**ETO Sterilization** **Manufacture** **Radiation (Gamma Sterilization)**

By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 Norderstedt 22851 Germany	**EU Representative**
J-Pac LLC 25 Centre Road Somersworth New Hampshire 03878-2927 USA	**Manufacture**
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**

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

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Subcontractor:	**Service(s) supplied**
The Secant Group, LLC 195 O'Neill Drive Quakertown, Pennsylvania 18951 USA	**Manufacture**
The Secant Group, LLC 430 South 8th Street Perkasie Pennsylvania 18944 USA	**Manufacture**
Xttrium Laboratories 1200 E Business Centre Dr. Mount Prospect, IL 60056 USA	**Crucial Supplier**

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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 (Pewankee) 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,Cardiovations, 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		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. Addition of Medical lasers and fibres to scope and incorporating the devices previously covered by Heartport QMS certificate CE 92659 into this certificate. 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.
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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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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Date	Reference Number	Action
15 December 2017	8660564	Addition of Ethicon, Inc. Athens, GA for suture raw material manufacturing. Addition of 'Packaging' as activity for Ethicon Inc., Ciudad Juarez, Mexico. Change of activity to 'ETO Sterilisation' from 'Sterilisation' for Ethicon Inc., San Angelo, Texas. Removal of "Endomentrial Ablation Systems (Sterile & Non-Sterile) from scope. Addition of 'Ethicon Endo-Surgery, Inc, Cincinnati', 'Ethicon Inc, Georgia' and 'Janssen Pharmaceutical, Inc. Athens', as significant subcontractors. Removal of Tissue Sealants for Internal Surgical Applications from scope. Change of name for Secant Medical Inc., Pennsylvania to The Secant Group, LLC. and change of street address. Administrative update to remove the duplicate entry for the significant subcontractor Plexus Corp. Correction of street number for Sterigenics, Charlotte.

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Date	Reference Number	Action
28 June 2018	8895429	Removal of absorbable adhesion prevention devices composed of Oxidized Regenerated Cellulose (ORC) (sterile), haemostasis device (absorbable & non-absorbable, sterile), pelvic organ prolapse urogynaecological surgical mesh (sterile), surgical bone wax (sterile), surgical support tapes (non-absorbable, sterile), temporary cardiac pacing wires (sterile), tissue fixation devices (absorbable, sterile), and urinary stress incontinence devices (sterile & non-sterile) from the certificate scope Removal of subcontractors: Availmed S.A. de C.V., CEA Medical Manufacturing, Ethicon Endo Surgery, Inc. (Cincinnati), Ethicon SARL, Manufacturas Zapaliname SA de CV, Plexus Corp, Sterigenics International, Inc (Fort Worth), Sterigenics US, LLC (Hayward), Sterigenics US, LLC (Corona), Sterigenics US, LLC (Salt Lake City), and Sterigenics (Hayward).

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Date	Reference Number	Action
		Addition of BASF Grenzach GmbH as crucial supplier of a medicinal substance and Synergy health Sterilization UK Ltd. for subcontract Gamma Sterilization. Addition of packaging to the service supplied for Gyrus Medical Limited. Administrative update to define the type of sterilization for subcontractors Johnson & Johnson do Brasil, Johnson & Johnson Medical GmbH, Johnson & Johnson Medical Ltd. (Livingston), Sterigenics SAS, and Sterigencis US, LLC. Administrative changes to the address for subcontractors Integra NeuroSciences, Philips Plastics Corporation, and Synergy Health Däniken AG.

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Date	Reference Number	Action
		Change of address for Sterigencis US, LLC from Glen Falls, New York to Queensbury, New York. Change of name for subcontractors STERIS Isomedix Services (El Paso, TX), STERIS Isomedix Services (Spartanburg, SC) and STERIS Isomedix Services (Whippany, NJ) to Isomedix Operations, Inc. Change of name for subcontractor STERIS Isomedix Services (Vega Alta) to Isomedix (Puerto Rico), Inc. Change of name for subcontractor Synergy Health Sterilisation UK Ltd to STERIS Applied Sterilization Technologies (Formerly Synergy Health Sterilization UK Ltd). Certificate renewal.
22 February 2019	7781191	Traceable to NB 0086.

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Date	Reference Number	Action
29 March 2021	3110232	Certificate Renewal. Addition of Synergy Health Sterilisation UK Ltd Moray Road, Elgin Industrial Estate Swindon, Wiltshire, SN2 8XS, UK Remove Steris Applied Sterilization technologies (Synergy Health Sterilization), Mora Road Elgin Industrial Estate, Swindon SN2 8NX, UK. Change of address for Intega LifeSciences Corporation to 1100 Campus Road, Princeton, New Jersey 08540, USA. Name change to Steris Isomedix Puerto Rico LLC, address update. Sterigenics SAS and Synergy Health Daeniken AG have requested to be removed from CE 00384. Remove Synergy Health Sterilization UK Ltd as subcontractor Addition of Nypro Healthcare Baja Inc. (a Jabil company) as a subcontractor Removal of Phillips Plastics: This subcontractor is listed in error. Addition of Xttrium Laboratories (Crucial Supplier).

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Date	Reference Number	Action
		Addition of Edwards Lifesciences (Contract EO Sterilizer). Remove Johnson and Johnson Medical Ltd located on Simpson Parkway Administrative update to address for J-Pac, LLC. Administrative update – addition of supplementary tables. Administrative update to subcontractor's service supplied to change 'gamma sterilization' to 'radiation (gamma sterilization)'. Administrative update to remove 'medicinal substances' from the list of services supplied by BASF Grenzach GmbH.

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USA

Date	Reference Number	Action
24 May 2021	3201570	Change of Legal Manufacturer address to 1000 Route 202, Raritan, New Jersey, 08869, USA Reformatting of scope expression to remove reference to non-absorbable sutures and ligatures, stainless steel suture and ligatures, non-synthetic sutures and ligatures and medicated sutures and ligatures Removal of the following mesh and sutures from certificate scope and/or device supplementary table: PROCEED SURGICAL MESH, MERSILENE Suture and MERSUTURE Suture, MONOCRYL Suture, VICRYL PLUS Antibacterial Suture, VICRYL RAPIDE Suture, PROLENE Suture, MERSILK and PERMA - HAND Braided Silk and Virgin Silk Non-Absorbable Suture, NUROLON Suture, PRONOVA Suture, ETHILON Suture and Stainless Steel Suture Removal from scope of a number of product codes for VICRYL Suture, PDS II Suture and BIOPATCH Dressings Removal of Subcontractors Ethicon Endo-Surgery, Inc., Nypro Healthcare Baja Inc., Isomedix Operations, Inc. (Spartanburg), Johnson & Johnson Medical (China) Ltd. and Steris Isomedix Puerto Rico LLC

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00384**

Date: **2021-05-24**

Issued To: **Ethicon, Inc.**
Also Trading as Ethicon Women's Health & Urology, a Division of Ethicon, Inc.
1000 Route 202
Raritan
New Jersey
08869
USA

Date	Reference Number	Action
		Removal of Crucial Supplier BASF Grenzach GmbH Administrative update to device schedule table to replace GYNECARE VERSAPOINT II System to GYNECARE VERSAPOINT Bipolar Electrosurgery System and GYNECARE VERSAPOINT II Bipolar Electrosurgery System. This is to align with device naming convention indicated in Declaration of Conformity

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00384**

Date: **2021-05-24**

Issued To: **Ethicon, Inc.**
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1000 Route 202
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New Jersey
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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
30 September 2022	3346723	Removal of GYNECARE VERSAPOINT Hysteroscopic Bi-polar Electrosurgical Instruments, Systems and Associated Electrodes (Sterile and Non-Sterile) from certificate scope expression and device schedule. Removal of Gyrus Medical Limited as a subcontractor for Design, Manufacture and Packaging. Removal of Janssen Pharmaceutical, Inc. as a subcontractor for manufacture. Removal of Design, ETO Sterilization, Manufacture, Packaging and Radiation (Gamma Sterilization) from services supplied by Johnson & Johnson Medical GmbH (Norderstedt). Removal of Sterigenics US, LLC (Queensbury) as a subcontractor for ETO Sterilization. Removal of Isomedix Operations, Inc (El Paso), Isomedix Operations, Inc (Whippany) and Synergy Health Sterilisation UK Ltd as subcontractors for Radiation (Gamma Sterilization).

30 September 2022

Ethicon, Inc.
Also Trading as Ethicon Women's Health
& Urology, a Division of Ethicon, Inc.
1000 Route 202
Raritan
New Jersey
08869
USA

To whom it may concern,

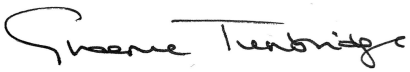
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00384	93/42/EEC Annex II excluding Section 4	3346723	Removal of GYNECARE VERSAPOINT Hysteroscopic Bi-polar Electrosurgical Instruments, Systems and Associated Electrodes (Sterile and Non-Sterile) from certificate scope expression and device schedule. Removal of Gyrus Medical Limited as a subcontractor for Design, Manufacture and Packaging. Removal of Janssen Pharmaceutical, Inc. as a subcontractor for manufacture. Removal of Design, ETO Sterilization, Manufacture, Packaging and Radiation (Gamma Sterilization) from services supplied by Johnson & Johnson Medical GmbH (Norderstedt). Removal of Sterigenics US, LLC (Queensbury) as a subcontractor for ETO Sterilization. Removal of Isomedix Operations, Inc (El Paso), Isomedix Operations, Inc (Whippany) and Synergy Health Sterilisation UK Ltd as subcontractors for Radiation (Gamma Sterilization).

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



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