

# EC Certificate - Production Quality Assurance

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

**No.****CE 01991****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 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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **02 July 1998**

Date: **25 April 2016**

Expiry Date: **01 July 2018**

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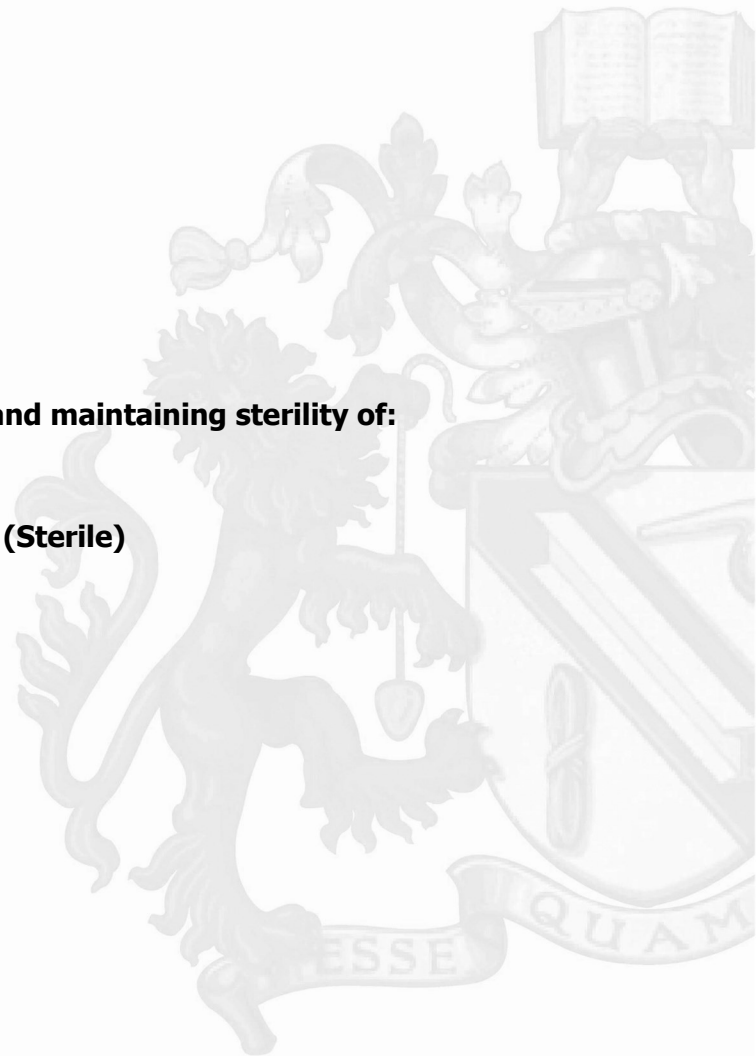
Page 1 of 2

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Certificate No: CE 01991

## Certificate Scope:

**The manufacture of:****Closed Wound Drains (Sterile)****Endoscopic Instruments (Sterile)****Elastic tubing to secure veins, arteries, nerves  
and ureters (Sterile)****Surgical support tapes (Non-Absorbable, Sterile)****Sutures (Sterile, Synthetic, Non-Absorbable)****Tissue Sealants and Adhesives for Topical  
Surgical Applications (Sterile)****Those aspects of manufacture related to securing and maintaining sterility of:****Cervical Access Cannula (Sterile)****Closed Wound Drainage Reservoir and Accessories (Sterile)****Hysteroscopic Sheaths (Sterile)****Umbilical Cord Tape (Sterile)**First Issued: **02 July 1998**Date: **25 April 2016**Expiry Date: **01 July 2018**

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## List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1, C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tijuana C.P. 22116 Mexico	<b>Manufacture</b> <b>Packaging</b>
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz.105 No. 20905 Int. A Col. Cd. Industrial Tijuana Baja California 22444 Mexico	<b>Manufacture</b> <b>Packaging</b>
ConMed Corporation 525 French Road Utica NY 13502 USA	<b>Manufacture</b>

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Subcontractor:	Service(s) supplied
Degania Medical Devices Pvt Ltd 251 Sector-6 IMT Manesar Gurgaon Haryana PIN-122050 India	<b>Manufacture Packaging</b>
Degania Silicone Limited Degania Bet 15130 Israel	<b>Manufacture</b>
Ethicon Endo-Surgery, Inc. 3801 University Boulevard SE Albuquerque, NM 87106 USA	<b>Sterilization</b>

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Subcontractor:	Service(s) supplied
Ethicon Inc 3348 Pulliam Street San Angelo Texas 76905 USA	<b>Manufacture Sterilization</b>
Ethicon Inc Calle Durango No. 2751 Lote Bravo Ciudad Juarez Chihuahua CP 32575 Mexico	<b>Manufacture</b>
Ethicon LLC Highway 183 Km. 8.3 San Lorenzo 00754 Puerto Rico USA	<b>Manufacture</b>

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Subcontractor:	Service(s) supplied
Johnson & Johnson Medical Ltd Simpson Parkway Kirkton Campus Livingston EH54 7AT United Kingdom	EU Representative
Phillips Plastics Corporation Short Run 705 Wisconsin Drive New Richmond Wisconsin 54017 USA	Manufacture Packaging
Sterigenics US, LLC 10821 Withers Cove Park Drive Charlotte NC 28278 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics 84 Park Road Glens Falls New York 12804 USA	ETO Sterilization
STERIS Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	Sterilization
STERIS Isomedix Services State Road 690 KM 1.7 Barrio Sabana Hoyos Vega Alta 00692 Puerto Rico USA	Sterilization

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### Subcontractor:

### Service(s) supplied

Vention Medical Costa Rica  
 Parque Zona Franca Metropolitana  
 Edificio 2C  
 Barreal de Heredia  
 40101  
 Costa Rica

**Manufacture**  
**Packaging**

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Date	Reference Number	Action
02 July 1998		First issued.
17 January 2002		Added Avail Medical Products to the list of sub-contractors.
26 March 2003		Certificate renewal.
07 April 2003		Added Ethicon Endo-Surgery to the list of sub-contractors.
29 April 2005		Transferred scope and sub contractors from Certificates CE 75621 and CE 73842, cancelling CE 75621, CE 73842, also addition of trading names, Gynecare, Johnson & Johnson Wound Management, Cardioventions, Ethicon, Inc. to the certificate.

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Page 1 of 7

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Date	Reference Number	Action
26 May 2006		<p>The wording of the scope was corrected to include the Class IIa Closed Wound Drainage System, Disposable Knot Pusher and Umbilical Tape under "manufacturing".</p> <p>The Class IIa Disposable Introducers, Specimen Retrieval Bags and Heart Positioner have also been added under "manufacturing". These derive from the Annex II Section 3 Full Quality Assurance Certificate CE 00384.</p> <p>The Class 1(s) Retention Suture Bridge has been added to the Limited Annex V certificate. These derive from the Annex II Section 3 Full quality Assurance Certificate CE 00384 Innovative Surgical Products, Inc, (Santa Ana), Johnson &amp; Johnson (Sherman) and Johnson &amp; Johnson (EI Paso) removed from the list of subcontractors.</p> <p>Accellent (Laconia), Avail Medical Products (Santa Ana), Innovative Surgical Products, Inc (Tustin), Steris Corporation Isomedex Services (Whippany) and (Puerto Rico) added to the list of subcontractors.</p> <p>Ion Beam Application (Queenbury) name has changed to "Sterigenics".</p>

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Page 2 of 7

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Date	Reference Number	Action
14 July 2008	7008428	Certificate Renewal. Removal of the Heart Positioner from the scope. Minor amendment to address of Conmed Corporation, Accellent Endoscopy & Avail Medical Products (Carnegie Avenue site). Replace the Avail Medical Products spectrum (one site with the Nancy Ridge address).
18 December 2008	7299527	Change to company division name in address. Addition of Availmed S.A. de C.v. (Mexico) subcontractor for manufacture and removal of Avail Medical Products, Inc subcontractor for manufacture. Removal of Disposable Knotpusher and minor changes to scope for clarity.
28 January 2010	7479853	Reformat of address. Extension to scope to include "sterile and Non-Sterile Medical Adhesives for Topical Applications". Addition of word 'cord' to Umbilical cord tapes. Addition of subcontractors Sterigenic, Withers Cove, James Alexander Corp, Ethicon LLC, San Lorenzo, Ethicon LLC, Guaynabo and Ethicon, Inc., Raleigh.
16 June 2010	7534049	Scope extension for "Sterile endoscopic instruments". Addition of subcontractors; Ethicon Kirkton, Phillips, Degania India and Degania Israel.

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Page 3 of 7

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Date	Reference Number	Action
30 November 2010	7611355	The Addition of "Also trading as Closure Medical Corp ., a Division of Ethicon Inc." to address.
31 March 2011	7652622	Update of Subcontractor address. Removal of disposable introducer and specimen retrieval bag from scope. Addition of sutures (sterile, synthetic, non-absorbable), and surgical support tapes (sterile) to certificate scope. Revised description for medical adhesives to 'tissue sealants and adhesives for topical surgical applications (sterile)'. Reformat of certificate scope on supplementary page.
26 September 2012	7867805	Correction of EU rep name and address . Addition of ATEK Medical, LLC as significant subcontractor. Correction of address of Avail Medical Products, Inc. Change of name of Innovative Surgical Products, Inc to Specialty Silicone Fabricators, Inc.

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Page 4 of 7

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Date	Reference Number	Action
14 May 2013	7983862	Removal of 'Surgical support tapes (Sterile), from scope. Addition of 'Johnson & Johnson Medical Limited, EH54 7AT as EU Representative.
23 May 2013	7945176	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.  The addition of 'Ethicon Inc, San Angelo' and 'Ethicon Inc, Chihuahua' as significant subcontractors.  Update to address for significant subcontractor 'Availmed S.A. de C.V. (Mexico)' and the removal of 'Avail Medical Products, California', 'James Alexander Corporation, New Jersey' and 'Speciality Silicone Fabricators, Inc, California' as significant subcontractors.
	7999121	Certificate Renewal.

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Page 5 of 7

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Date	Reference Number	Action
19 August 2014	8193704	Removal of Also trading as names J&J Wound Management, Gynecare, Closure Medical. Removal of subcontractors Ethicon Inc, Raleigh and Ethicon S.A.S. Removal of Would Closure Strips from scope. Replacement of EU reps with Johnson & Johnson Medical Ltd. Removal of ATEK Medical as subcontractor. Addition of Vention Medical as subcontractor. Administrative update to certificate format.

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Page 6 of 7

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Date	Reference Number	Action
25 April 2016	8332735	<p>Removal of word "systems" from closed wound drains scope wording.</p> <p>Change for Umbilical Cord tape from full Annex V coverage to limited coverage.</p> <p>Removal of fixations clips, polypropylene buttons and retention suture bridges from scope.</p> <p>Addition of Closed Wound Drainage Reservoir and accessories (Sterile) to scope.</p> <p>Removal of Accellent Inc as significant subcontractor.</p> <p>Removal of Ethicon LLC Guaynabo as significant subcontractor.</p> <p>Addition of packaging to Phillips, Availmed and Degania Medical Devices.</p> <p>Addition of Availmed S.A. de C.V. C. Industrial Lt as significant subcontractor for manufacturing and packaging.</p>

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Page 7 of 7

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