

# 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****...making excellence a habit.™**

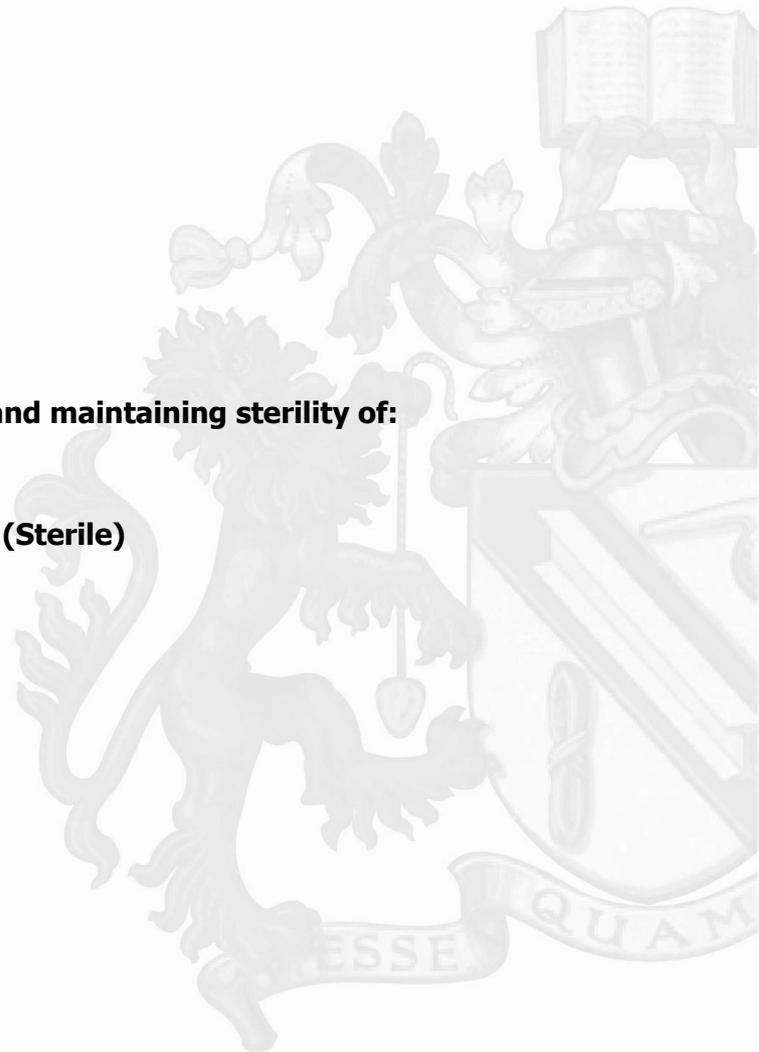
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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed 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 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

**Manufacture  
Packaging**

Availmed S.A. de C.V.  
C. Industrial Lt. 001 Mz.105  
No. 20905 Int. A  
Col. Cd. Industrial  
Tijuana  
Baja California  
22444  
Mexico

**Manufacture  
Packaging**

ConMed Corporation  
525 French Road  
Utica  
NY 13502  
USA

**Manufacture**

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

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

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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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# EC Certificate - Production Quality Assurance Certificate History

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