

EC Certificate - Full Quality Assurance System

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

No. CE 661656
Issued To: KCI USA, Inc.
 12930 IH 10 West
 San Antonio
 Texas
 78249
 USA

In respect of:

Design, development, and manufacture of powered and non-powered negative pressure wound therapy pumps and associated sterile foam dressing kits and tube sets, silver foam dressing kits, abdominal dressing kits, and electrically powered dermatome and associated accessories.

Those aspects of Annex II concerned with securing and maintaining the sterility of accessories for negative pressure wound therapy systems.

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):



Stewart Brain, Head of Compliance & Risk - Medical Devices



First Issued: **2017-03-03**

Date: **2018-07-17**

Expiry Date: **2020-03-07**

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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.

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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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 Date: **2018-07-17**
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Subcontractor:	Service(s) supplied
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
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior C1, E2, La Mesa Tijuana C.P 22116 Mexico	Manufacture
Avery Dennison Medical 7100 Lindsay Drive Mentor Ohio 44060 USA	Crucial Supplier



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Subcontractor:	Service(s) supplied
Bemis Manufacturing Company 300 Mill Street Sheboygan Falls Wisconsin 53085 USA	Manufacture
Brightwake Limited Lowmoor Business Park Kirkby in Ashfield Nottinghamshire NG17 7JZ United Kingdom	Manufacture Packaging
First Water Ltd Hilldrop Lane Ramsbury Marlborough Wiltshire SN8 2RB United Kingdom	Manufacture



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Subcontractor:	Service(s) supplied
FXI 3005 Commercial road Fort Wayne Indiana USA	Crucial Supplier
Isomedix Operations, Inc. 1435 Isomedix Place El Paso Texas 79936 USA	Gamma Sterilization
KCI Manufacturing IDA Business & Technology Park Dublin Road Athlone Co. Westmeath Ireland	EU Representative Manufacture Packaging



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Subcontractor:	Service(s) supplied
KCI Polymedics BVBA Ambachtslaan 1031 3990 Peer Belgium	Manufacture
KCI USA, Inc 6203 Farinon Drive San Antonio Texas 78249 USA	Design
Noble Biomaterials, Inc. 300 Palm St. Scranton PA 18505 USA	Crucial Supplier



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Subcontractor:	Service(s) supplied
Reliable Silver Rochester Silver Works LLC Eastman Business Park 100 Latona Road, Gate 340, Building 143 Rochester New York 14652-3651 USA	Crucial Supplier
Scapa Tapes, North America, LLC 5900 Middle View Way Knoxville Tennessee 37909 USA	Crucial Supplier
Sterigenics Belgium (Fleurus) SA Zoning Industriel de Fleurus Avenue De L'Esperance Fleurus B-6220 Belgium	Gamma Sterilization



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Service(s) supplied

Sterigenics UK Limited
 Cotes Park Estate
 Somercotes
 Alfreton
 DE55 4NJ
 United Kingdom

ETO Sterilization

Sterigenics US, LLC
 1401 Morgan Circle
 Tustin
 California 92780
 USA

Gamma Sterilization

Sterigenics US, LLC
 344 Bonnie Circle
 Corona
 California 92880
 USA

Gamma Sterilization



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Subcontractor:	Service(s) supplied
STERIS Applied Sterilization Technologies (Formerly Synergy Health Applied Sterilization Technologies) Moray Road, Elgin Industrial Estate Swindon SN2 8XS UK	Gamma Sterilization
Synergy Health AST, Etten-Leur Soeverijnstraat 2 Etten-Leur 4879 NN The Netherlands	Gamma Sterilization
Synergy Health Ireland Ltd (Synergy Health- AST- Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	ETO Sterilization



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Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Bradford) Roysdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	Gamma Sterilization
Synergy Health Westport Ltd (Synergy Health – AST – Westport) Lodge Road Westport County Mayo Ireland	Gamma Sterilization
Systagenix Wound Management Limited (an affiliate of Systagenix Wound Management Manufacturing Limited) Gargrave North Yorkshire BD23 3RX United Kingdom	Gamma Sterilization



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Subcontractor:

Service(s) supplied

Venusa de Mexico S.A. de R.L. de C.V.
 A Lake Region Medical Company
 Calle Hertz 1525
 Parque Industrial J. Bermudez
 Chihuahua
 32470 Ciudad Juarez
 Mexico

Manufacture



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Certificate History

Certificate No: **CE 661656**
 Date: **2018-07-17**
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Date	Reference Number	Action
03 March 2017	8604887	First issue. Transfer from another Notified Body.



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
 A member of BSI Group of Companies.

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Current	8869059	<p>Extension to scope to include electrically powered dermatome, therapy pumps, silver foam dressing kits, abdominal dressing kits. Those aspects of Annex II concerned with securing and maintaining sterile conditions of accessories for negative pressure wound therapy systems.</p> <p>Change of EU Rep from KCI Medical Products (UK), Ltd. (Dorset) to KCI Manufacturing (Athlone).</p> <p>Addition of significant subcontractors Lake Region Medical, Isomedix Operations, Inc., Availmed S.A. de C.V., Sterigenics US, LLC (Tustin), Sterigenics US, LLC (Corona), Bemis Manufacturing Company, Synergy Health Ireland Ltd, KCI Polymedics BVBA, First Water, Sterigenics-Fleurus, Synergy Health Ede Bv, Synergy Health Sterilisation Uk Ltd (Bradford), Synergy Health Westport Ltd, Systagenix Wound Management Limited Gargrave, and STERIS Applied Sterilization Technologies, Synergy Health AST (Etten-Leur, The Netherlands).</p> <p>Addition of Crucial Suppliers Noble Fiber Technologies LLC, Avery Dennison – Medical, Scapa Tapes North America, Inc, FXI, and Reliable Silver.</p>
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