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By Royal Charter

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**

Digitally signed by Kalcev Ghennadi
Date: 2019.07.08 15:59:09 EEST
Reason: MoldSign Signature
Location: Moldova

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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

Subcontractor:	**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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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 Soevereinstraat 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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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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:

Certificate No:	**CE 661656**
Date:	**2018-07-17**
Issued To:	**KCI USA, Inc.** **12930 IH 10 West** **San Antonio** **Texas** **78249** **USA**

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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661656**

Date: **2018-07-17**

Issued To: **KCI USA, Inc.**
12930 IH 10 West
San Antonio
Texas
78249
USA

Date	Reference Number	Action
03 March 2017	8604887	First issue. Transfer from another Notified Body.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661656**

Date: **2018-07-17**

Issued To: **KCI USA, Inc.**
12930 IH 10 West
San Antonio
Texas
78249
USA

Current	8869059	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. Change of EU Rep from KCI Medical Products (UK), Ltd. (Dorset) to KCI Manufacturing (Athlone). 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). Addition of Crucial Suppliers Noble Fiber Technologies LLC, Avery Dennison – Medical, Scapa Tapes North America, Inc, FXI, and Reliable Silver.

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

KCI USA, Inc.
12930 IH 10 West
San Antonio
Texas
78249
USA

Holds Certificate Number: **MD 673264**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Manufacture of NPT (Negative Pressure Therapy) Systems (powered and non-powered), including negative pressure therapy units and their associated disposable components, therapy units with instillation capability and their associated disposable components, silver dressing and Epidermal Harvesting System.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-12-12
Latest Revision Date: 2019-02-28

Effective Date: 2019-02-28
Expiry Date: 2022-02-27

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Certificate No: **MD 673264**

Location	Registered Activities
KCI USA, Inc. 12930 IH 10 West San Antonio Texas 78249 USA	Design and Manufacture of NPT (Negative Pressure Therapy) Systems (powered and non-powered), including negative pressure therapy units and their associated disposable components, therapy units with instillation capability and their associated disposable components, silver dressing and Epidermal Harvesting System.
KCI USA, Inc. San Antonio 2 6203 Farinon Drive San Antonio Texas 78249 USA	Design, Regulatory, Quality, Human Resources and Information Technology of NPT (Negative Pressure Therapy) Systems (powered and non-powered), including negative pressure therapy units and their associated disposable components, therapy units with instillation capability and their associated disposable components, silver dressing and Epidermal Harvesting System.
KCI USA, Inc. San Antonio 3 5850 Farinon Drive San Antonio Texas 78249 USA	Manufacture, Inspection and repair of powered NPT (Negative Pressure Therapy) Systems, including negative pressure therapy units, therapy units with instillation capability and Epidermal Harvesting Systems.

Original Registration Date: 2017-12-12
Latest Revision Date: 2019-02-28

Effective Date: 2019-02-28
Expiry Date: 2022-02-27

DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH10 West
San Antonio, TX 78249
U.S.A.

KCI USA, Inc. declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC and the Medical Devices (Amendment) Regulation 2008 no 2936 and carry the CE mark accordingly.

PRODUCT IDENTIFICATION

V.A.C.® GranuFoam™ Dressings *featuring SensaT.R.A.C.™ Technology*

M8275051/5 and M8275051/10 V.A.C.® GranuFoam™ Dressing Small
M8275052/5 and M8275052/10 V.A.C.® GranuFoam™ Dressing Medium
M8275053/5 and M8275053/10 V.A.C.® GranuFoam™ Dressing Large
M8275065/5 V.A.C.® GranuFoam™ Dressing X- Large
M8275075/5 and M8275075/10 V.A.C.® GranuFoam™ Dressing Round
M8275081/5 and M8275081/10 V.A.C.® GranuFoam™ Thin Dressing

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive

Signed for and on behalf of KCI USA, Inc., San Antonio, Texas, U.S.A.

Veronique Smith
Senior Director, Regulatory Affairs

April 20, 2015
Date of Issue

REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. "INTERNATIONAL GROUP" IDNO 1015600021387 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH 10 West
San Antonio, TX 78249
U.S.A.

KCI USA, Inc. declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC as amended by directive 2007/47/EC and the Medical Devices (Amendment) Regulation 2008 no. 2936 and carry the CE mark accordingly.

PRODUCT IDENTIFICATION

Sterile V.A.C.® Disposable Accessories

V.A.C.® Drape - M6275009/10
SensaT.R.A.C.™ Pad featuring SensaT.R.A.C.™ Technology – M8275057/10
V.A.C.® Y-Connector – M6275066/5 and M6275066/10

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive

Signed for and on behalf of KCI USA, Inc. San Antonio, Texas, U.S.A.

Veronique Smith, Senior Director, Regulatory Affairs

March 16, 2015
Date of Issue

REPUBLICA MOLDOVA mun. CHIŞINĂU S.R.L. "INTERNATIONAL GROUP" IDNO 1015600021387 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

MANUFACTURER

KCI USA, Inc.
12930 IH10 West
San Antonio, TX 78249
U.S.A.

KCI USA, Inc. declares that the products herewith comply with the requirements of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC and the Medical Devices (Amendment) Regulation 2008 no. 2936 and carry the CE mark accordingly.

PRODUCT IDENTIFICATION

InfoV.A.C./V.A.C. Ulta 500mL Canisters with gel, REF M8275063/5, M8275063/10, M8275063/1
InfoV.A.C./V.A.C. Ulta 500mL Canisters without gel, REF M8275071/5, M8275071/10
InfoV.A.C./V.A.C. Ulta 1000mL Canister with gel, REF M8275093/5

AUTHORIZED REPRESENTATIVE

KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom

REGISTRATION INFORMATION

Notified body/ID#	**CE Certificate Number**
AMTAC/0473	674-01 A CE

CONFORMITY ASSESSMENT

Device Classification	**Route to Compliance**
Class IIb Rule 4	Annex II (excluding section 4) of the Medical Device Directive 93/42/EEC Council directive as amended by Directive 2007/47/EC

Signed for and on behalf of KCI USA, Inc.,

Veronique Smith
Senior Director, Regulatory Affairs
San Antonio, Texas, U.S.A.

May 22, 2015
Date of Issue