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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-03-03** Date: **2020-03-03** Expiry Date: **2024-05-26**

Digitally signed by Kalcev Ghennadi
Date: 2021.05.11 10:33:35 EEST
Reason: MoldSign Signature
Location: Moldova

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Supplementary Information to CE 661656

Issued To:

KCI USA, Inc.
12930 IH 10 West
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Number	Device Name	Intended purpose per IFU
Class III		
---	V.A.C.® GRANUFOAM SILVER™ DRESSINGS	See CE 673268
Class IIb		
GMDN 61145	V.A.C. VERAFLO™ Dressings	Negative pressure wound therapy dressings with instillation, for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 58202	V.A.C. VIA™ Negative Pressure Therapy System	Negative pressure wound therapy pump, dressings, and canisters for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® GRANUFOAM™ Dressings	Negative pressure wound therapy dressings for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN 47406	V.A.C. WHITEFOAM™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® SIMPLACE™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 47406	V.A.C.® GRANUFOAM™ Bridge Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
GMDN 60884	Nanova Therapy System	Non-powered negative pressure wound therapy unit and dressings for use on chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.

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Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN 47406	SNAP™ Dressings	Negative pressure wound therapy dressing for use on chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.
Class IIa		
NBOG Codes MD 1100, MD 0100 and MDS 7006	V.A.C.ULTA™ Negative Pressure Wound Therapy System or V.A.C.ULTA 4 THERAPY Negative Pressure Wound Therapy System (with V.A.C.VeraLink Cassette and V.A.C.VeraT.R.A.C Duo)	---
NBOG Codes MD 1100	V.A.C.RX4™ Negative Pressure Wound Therapy System	---
NBOG Codes MD 1100	INFOV.A.C.™ Negative Pressure Wound Therapy System	---

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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG Codes MD 1100	ActiV.A.C. Negative Pressure Therapy System	---
NBOG Codes MD 1100	VAC Simplicity Negative Pressure Therapy Unit	---
NBOG Codes MD 1100, MD 0301 and MDS 7006	ABThera Open Abdomen Negative Pressure Therapy System (with ABThera dressings)	---
NBOG Codes MD 1100, MD 0100 and MDS 7006	Cellutome Epidermal Harvesting System (Harvesters, Control Unit, Vacuum Head)	---
NBOG Codes MD 1100	SNAP™ Therapy Cartridge	---
NBOG Codes MD 1100, MD 0301 and MDS 7006	Prevena Incision Management System	---

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Number	Device Name	Intended purpose per IFU
Class Is		
NBOG Code MD 0100 and MDS 7006	V.A.C. Freedom Canisters	---
NBOG Code MD 0100 and MDS 7006	V.A.C.® Tubing Cap	---
NBOG Code MD 0301 and MDS 7006	V.A.C.® Drape	---
NBOG Code MD 0100 and MDS 7006	SENSAT.R.A.C.™ Pad	---
NBOG Code MD 0100 and MDS 7006	V.A.C.® Y-connector	---
NBOG Code MD 0301 and MDS 7006	V.A.C.® Gel	---

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Number	Device Name	Intended purpose per IFU
Class Is		
NBOG Code MD 0100 and MDS 7006	Canisters for INFOV.A.C.™ and V.A.C. ULTA™ Therapy Systems	---
NBOG Code MD 0301 and MDS 7006	SNAP™ SecurRing Hydrocolloid	---
NBOG Code MD 0100 and MDS 7006	Canister for ACTIV.A.C. Therapy System	---
NBOG Code MD 0100 and MDS 7006	ABThera Open Abdomen Tubing Set	---

First Issued: **2017-03-03** Date: **2020-03-03** Expiry Date: **2024-05-26**

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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:	**2020-03-03**
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 C.P. 22444 Mexico	**Manufacture**
Avery Dennison Medical 7100 Lindsay Drive Mentor Ohio 44060 USA	**Crucial Supplier**
Bemis Manufacturing Company 300 Mill Street Sheboygan Falls Wisconsin 53085 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Brightwake Limited Lowmoor Business Park Kirkby in Ashfield Nottinghamshire NG17 7JZ United Kingdom	**Manufacture** **Packaging**
First Water Limited Hilldrop Lane Ramsbury Marlborough SN8 2RB United Kingdom	**Manufacture**
FXI, Inc. 3005 Commercial Road Fort Wayne IN 46809 United State of America	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
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**
KCI Polymedics BVBA Ambachtslaan 1031 3990 Peer Belgium	**Manufacture**

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Subcontractor:	**Service(s) supplied**
KCI USA, Inc 6203 Farinon Drive San Antonio Texas 78249 USA	**Design**
Noble Biomaterials, Inc. 300 Palm Street Scranton Pennsylvania 18505 USA	**Crucial Supplier**
Rochester Silver Works, LLC Eastman Business Park, 100 Latona Rd, Gate 340, Building 143 Rochester NY 14652-3651 USA	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Scapa Tapes, North America, LLC 5900 Middle View Way Knoxville Tennessee 37909 USA	**Crucial Supplier**
SCAPA Tapes, North America, LLC 2565 Bertelkamp Lane, Knoxville Tennessee 37931 USA	**Crucial Supplier**
Sterigenics Belgium (Fleurus) SA Zoning Industriel de Fleurus Avenue De L'Esperance 1 Fleurus, Hainaut B-6220 Belgium	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**
Sterigenics US, LLC 1401 Morgan Circle Tustin Califonia 92780 USA	**Gamma Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
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**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsadale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Reading) Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	**Gamma Sterilization**
Synergy Health Westport Ltd (Synergy Health – AST – Westport) Lodge Road Westport County Mayo Ireland	**Gamma Sterilization**
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. de R.L. de C.V. a Lake Region Medical Company Calle Hertz 1525 Parque Industrial Antonio 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: **2020-03-03**

Issued To: **KCI USA, Inc.**
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Date	Reference Number	Action
03 March 2017	8604887	First issue. Transfer from another Notified Body.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661656**
Date: **2020-03-03**
Issued To: **KCI USA, Inc.**
12930 IH 10 West
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Date	Reference Number	Action
17 July 2018	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.

EC Certificate - Full Quality Assurance System Certificate History

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Date: **2020-03-03**

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Date	Reference Number	Action
12 February 2019	8695070	Traceable to NB 0086.
18 April 2019	9704629	Addition of new devices (Prevena Incision Management System, ULTA 4 THERAPY V.A.C. Negative Pressure Wound Therapy System, and the V.A.C.RX4™ Negative Pressure Wound Therapy System). Administrative updates to add supplementary product information to certificate.
11 November 2019	3040052	Add a second location to an approved Crucial Supplier (SCAPA)
Current	3084383	Certificate Renewal. Removal of the following Subcontractors: Availmed S.A de C.V, Av. Paseo Reforma No. 8950 (Mexico) Steris Applied Sterilisation Technologies (Swindon) Addition of Subcontractor Synergy Health AST Reading Minor updates to Subcontractor Addresses of First Water Limited, FXI Inc., Noble Biomaterials Inc., Rochester Silver, Works LLC, Sterigenics Belgium (Fleurus) SA, Sterigenics Alferton, Systagenix Wound Management Manufacturing Limited and Venusa de Mexico S.de R.L. de C.V. Update to product table (Inclusion of NBOG codes)