

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F003661

Holds Certificate No:

MDSAP 698781

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-04-10

Effective Date: 2023-02-28

Expiry Date: 2026-02-27



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 698781**

Registered Scope:

The design, development, manufacture and servicing 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 epidermal harvesting system for the area of wound therapy.



Original Registration Date: 2020-04-10

Effective Date: 2023-02-28

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 698781**

Location	Registered Activities
KCI USA, Inc. 12930 IH 10 West San Antonio Texas 78249 USA Facility ID Number: F003661	The design, development, manufacture and servicing 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 epidermal harvesting system for the area of wound therapy.
KCI USA, Inc. San Antonio 2 6203 Farinon Drive San Antonio Texas 78249 USA Facility ID Number: F003661	The design and development 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 epidermal harvesting system for the area of wound therapy.
KCI USA, Inc. San Antonio 3 5850 Farinon Drive San Antonio Texas 78249 USA Facility ID Number: F003661	Manufacture and servicing of powered negative pressure wound therapy pumps and epidermal harvesting system for the area of wound therapy.

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