



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 nonpowered), 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.

SM Sr.

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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...making excellence a habit."

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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 the BSI Group of Companies.

Certificate No: MD 673264

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

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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