

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Augustine Temperature Management, LLC
6581 City West Parkway
Eden Prairie
Minnesota
55344
USA

Facility ID Number: F005083

Holds Certificate No:

MDSAP 715042

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure, Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure; 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

The design and manufacture of patient temperature management systems and related nonsterile accessories including warming mattresses with electrosurgical grounding pads.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-05-07

Effective Date: 2021-05-07

Expiry Date: 2024-05-06



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 715042**

Location

Augustine Temperature Management, LLC
6581 City West Parkway
Eden Prairie
Minnesota
55344
USA
Facility ID Number: F005083

Registered Activities

Design and development, manufacture and distribution of patient warming systems.

Augustine Temperature Management, LLC
7656 West 78th Street
Minneapolis
Minnesota
55439
USA

Manufacturing and distribution.



Original Registration Date: 2021-05-07

Effective Date: 2021-05-07

Expiry Date: 2024-05-06

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
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.