

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

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

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-01-04

Effective Date: 2023-01-04

Expiry Date: 2024-05-06



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 715042**

Location	Registered Activities
Augustine Temperature Management, LLC 6581 City West Parkway Eden Prairie Minnesota 55344 USA Facility ID Number: F005083	Design and development of patient warming systems.
Augustine Temperature Management, LLC 7656 West 78th Street Minneapolis Minnesota 55439 USA	Manufacturing, servicing, and distribution.



Original Registration Date: 2023-01-04

Effective Date: 2023-01-04

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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.