

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö
Sweden

Facility ID Number: F000046

Holds Certificate No:

MDSAP 695480

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; Brasil - 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, 21 CFR 821

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-03-26

Effective Date: 2021-07-29

Expiry Date: 2024-01-05



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 695480**

Registered Scope:

The design, manufacture, distribution, service, support and installation of patient transfer/handling systems, with or without scales, and related accessories, and of bathing systems with optional hydromassage, hydrosound and disinfection.

The design, manufacture and distribution of pressure relieving mattresses and seating, intermittent compression systems, pumps and accessories, hospital, nursing home and homecare beds, couches, patient trolleys, birthing beds, and Intensive Therapy Unit beds and accessories.

The design, manufacture, distribution, sales, service, support and installation of equipment and accessories for disinfection.



Original Registration Date: 2019-03-26

Effective Date: 2021-07-29

Expiry Date: 2024-01-05

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This certificate remains the property of BSI and shall be returned immediately upon request.

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

Certificate No: **MDSAP 695480**

Location	Registered Activities
Arjo (Suzhou) Co., Ltd. No. 158 Fangzhou Road Suzhou Industrial Park, Suzhou 215024 Jiangsu China Facility ID Number: F004821	The design, manufacture and distribution of pressure relieving mattresses and seating, intermittent compression systems, associated pumps and accessories.
ArjoHuntleigh Polska Sp. z o.o. ul. Ks. Wawrzyniaka 2 62-052 Komorniki Poland Facility ID Number: F003878	The design, manufacture and distribution of pressure relieving mattresses and seating, hospital, nursing home and homecare beds, couches, patient trolleys, Intensive Therapy Unit beds, intermittent compression systems, pumps and sterile and non-sterile intermittent compression garments, patient transfer/handling systems and accessories, bathing systems with optional hydromassage, hydrosound and disinfection.
ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö Sweden Facility ID Number: F000046	<p>The design, manufacture, distribution, service, support and installation of patient transfer/handling systems, with or without scales, and related accessories, and of bathing systems with optional hydromassage, hydrosound and disinfection.</p> <p>The design, manufacture and distribution of pressure relieving mattresses and seating, intermittent compression systems, pumps and accessories, hospital, nursing home and homecare beds, couches, patient trolleys, birthing beds, and Intensive Therapy Unit beds and accessories.</p> <p>The design, manufacture, distribution, sales, service, support and installation of equipment and accessories for disinfection.</p>

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