

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

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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

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

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-26

Effective Date: 2024-01-06

Expiry Date: 2027-01-05



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 695480**

Registered Scope:

The design, manufacture, distribution, servicing, 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, servicing, and installation of equipment and associated accessories for disinfection.



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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.

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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 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	Management, regulatory affairs, design and development, purchasing, sales and customer service.



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