

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Össur hf  
Grjótháls 1-5  
Reykjavík  
110  
Iceland

Facility ID Number: F001444

Holds Certificate No:

**MDSAP 699071**

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

The design, manufacture and distribution of external prosthetic devices, orthotic devices and rehabilitation circulation packs.

The manufacture and distribution of sterile and non-sterile traction devices.

The service of external prosthetic devices and orthotic devices.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-12-16

Effective Date: 2021-03-25

Expiry Date: 2022-12-15



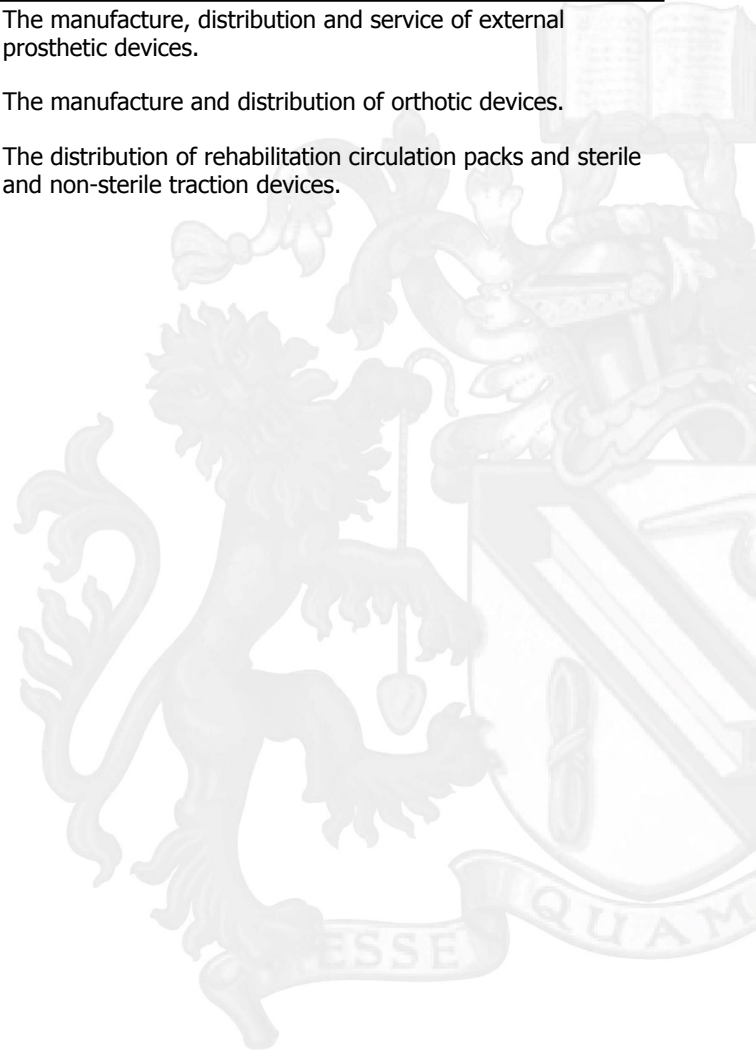
BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 699071**

Location	Registered Activities
Össur hf Grjótháls 1-5 Reykjavik 110 Iceland Facility ID Number: F001444	The design, manufacture and distribution of external prosthetic devices, orthotic devices and rehabilitation circulation packs.  The manufacture and distribution of sterile and non-sterile traction devices.  The service of external prosthetic devices and orthotic devices.
Ossur Americas 680 Grove Rd. West Deptford New Jersey 08086 USA Facility ID Number: F003629	The manufacture, distribution and service of external prosthetic devices.  The manufacture and distribution of orthotic devices.  The distribution of rehabilitation circulation packs and sterile and non-sterile traction devices.



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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](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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