

# 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**

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. 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 service of external prosthetic devices and orthotic devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-16

Effective Date: 2022-12-16

Expiry Date: 2025-12-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 699071**

Location

Össur hf.  
Grjótháls 1-5  
Reykjavík  
110  
Iceland  
Facility ID Number: F001444

Registered Activities

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



Original Registration Date: 2019-12-16

Effective Date: 2022-12-16

Expiry Date: 2025-12-15

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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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A Member of the BSI Group of Companies.