

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Össur Iceland 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, distribution and service of external prosthetic devices and accessories, orthotic devices and accessories, the manufacture of custom orthotic devices, sterile and non-sterile traction devices, the assembly and kitting of external prosthetic devices, and pump devices for cardiovascular applications. The manufacture of rehabilitation circulation packs.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-12-16

Effective Date: 2020-08-17

Expiry Date: 2022-12-15



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 699071**

Location

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

Ossur Americas
680 Grove Rd.
West Deptford
New Jersey
08086
USA
Facility ID Number: F003629

Registered Activities

The design, manufacture, distribution and service of external prosthetic devices and accessories, orthotic devices and accessories, the manufacture of custom orthotic devices, sterile and non-sterile traction devices, the assembly and kitting of external prosthetic devices, and pump devices for cardiovascular applications. The manufacture of rehabilitation circulation packs.

The assembly and distribution of external prosthetic devices and orthotic 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](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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