

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. 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

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: 2024-02-21

Expiry Date: 2025-12-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 699071**

Location	Registered Activities
Össur hf. Grjótháls 1-5 Reykjavík 110 Iceland Facility ID Number: F001444	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: 2024-02-21 Expiry Date: 2025-12-15

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.