



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Össur hf. Grjótháls 1-5 Reykjavik 110 Iceland

Holds Certificate Number:

MD 629190

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

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: 2015-01-21 Latest Revision Date: 2023-02-07



Effective Date: 2023-01-30 Expiry Date: 2026-01-29

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 629190

| Location | Registered Activities |
|--|---|
| Össur hf. Grjótháls 1-5 Reykjavik 110 Iceland | The design, manufacture and distribution of external prosthetic devices, orthotic devices and rehabilitation circulation packs. The service of external prosthetic devices and orthotic devices. |
| Össur Europe BV De Schakel 70 5651 GH Eindhoven The Netherlands | The manufacture, distribution and service of external prosthetic devices and orthotic devices. |
| Ossur Americas 680 Grove Rd. West Deptford New Jersey 08086 USA | The manufacture, distribution and service of external prosthetic devices. The manufacture and distribution of orthotic devices. The distribution of rehabilitation circulation packs. |
| Ossur UK Unit 1 S:Park (Spark Business Park) Hamilton Road Stockport SK1 2AE United Kingdom | The distribution of orthotic devices. |
| Ossur North America Blvd.Hector Teran Teran 2102 Col. Cañon del Padre Tijuana Baja California 22206 Mexico | The manufacture, distribution and service of external prosthetic devices and orthotic devices. Distribution of rehabilitation circulation packs. |
| Össur Iceland ehf. Grjótháls 1-5 Reykjavík 110 Iceland | The design and manufacture of external prosthetic devices, orthotic devices and rehabilitation circulation packs. The service of external prosthetic devices. |
| Touch Bionics Ltd Integration House The Alba Campus Rosebank EH54 7EG United Kingdom | The design, manufacture and service of external prosthetic devices. |

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