

Certificate of Registration

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

This is to certify that:

Össur hf.
Grjótháls 1-5
Reykjavík
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 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: 2015-01-21

Latest Revision Date: 2021-02-12

Effective Date: 2020-01-30

Expiry Date: 2023-01-29

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Certificate No: **MD 629190**

Location	Registered Activities
Össur hf Grjótháls 1-5 Reykjavík 110 Iceland	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.
Össur Europe BV De Schakel 70 5651 GH Eindhoven The Netherlands	The manufacture, distribution and service of external prosthetic devices and orthotic devices. The distribution of sterile and non-sterile traction devices.
Ossur Americas 27051 Towne Centre Drive, Suite 100 Foothill Ranch California 92610 USA	The design of 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 and sterile and non-sterile traction devices.
Ossur UK Unit 1 S:Park (Spark Business Park) Hamilton Road Stockport SK1 2AE United Kingdom	The distribution of orthotic devices and sterile and non-sterile traction 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.

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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 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.
Össur Deutschland GmbH Logistikpark 7A Bayreuth 95448 Germany	The design of external prosthetic devices and accessories.
Touch Bionics Ltd Unit 3 Ashwood Court Oakbank Park Way Livingston EH53 0TH United Kingdom	The design, manufacture and service of external prosthetic devices.



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