

Australian Government

Department of Health Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Ossur Australia Pty Ltd

for approval to supply

Ossur Australia Pty Ltd - Traction unit, component, noninvasive

| ARTG Identifier | 183559 | |
|------------------|---------------------------------------|--|
| ARTG Start Date | 19/05/2011 | |
| Product Category | Medical Device Included Class 1 | |
| GMDN | 33653 | |
| GMDN Term | Traction unit, component, noninvasive | |
| Intended Purpose | Traction Frame and accessories | |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|---|-----------------------|
| Ossur HF | Grjothals 1-5 110 , Reykjavik , Iceland | |

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

 The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.

- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Traction unit, component, noninvasive

Product Specific Conditions

· No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 183559 ARTG Start Date: 19/05/2011