

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 - Orthosis, arm, wrist/hand, unit

| ARTG Identifier | 135045 | |
|------------------|--|--|
| ARTG Start Date | 19/02/2007 | |
| Product Category | Medical Device Included Class 1 | |
| GMDN | 41459 | |
| GMDN Term | Orthosis, arm, wrist/hand, unit | |
| Intended Purpose | This is an orthosis that encompassess the wrist joint and the hand. The device is body worn. | |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|--|-----------------------|
| Ossur Hf | 27412-A Laguna Hills Drive ALISO VIEJO , CALIFORNIA , 92656 United States Of America | |

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. Orthosis, arm, wrist/hand, unit

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: 135045 ARTG Start Date: 19/02/2007