## 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, leg, ankle/foot, unit

ARTG Identifier 135046

ARTG Start Date 19/02/2007

Product Category Medical Device Included Class 1

**GMDN** 36206

GMDN Term Orthosis, leg, ankle/foot, unit

Intended Purpose An orthosis that encompassess the ankle joint and the whole or part of

the foot. This device is body worn.

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. Orthosis, leg, ankle/foot, 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: 135046 ARTG Start Date: 19/02/2007