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, knee, unit

ARTG Identifier 135047

ARTG Start Date 19/02/2007

Product Category Medical Device Included Class 1

GMDN 41065

GMDN Term Orthosis, leg, knee, unit

Intended Purpose An orthosis that encompasses the knee joint. This device is body worn.

Stabilises, protects and/or supports the knee joint and is used for conditions requiring unloading of the joint including osteoarthritis,

meniscal tears.

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, knee, 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: 135047 ARTG Start Date: 19/02/2007