

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 - Prosthesis, external, leg, trans-tibial, component, socket

ARTG Identifier 141295

ARTG Start Date 28/06/2007

Product Category Medical Device Included Class 1

GMDN 41152

GMDN Term Prosthesis, external, leg, trans-tibial, component, socket

Intended Purpose To accommodates the residual limb and acts as the interface between

the body and the prosthesis for transtibial amputation.

Manufacturer Details	Address	Certificate number(s)
Ossur HF	5 Grjothals , Reykjavik , IS-110 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. Prosthesis, external, leg, trans-tibial, component, socket

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: 141295 ARTG Start Date: 28/06/2007