



Australian Register of Therapeutic Goods Certificate

Issued to

Ossur Australia Pty Ltd

for approval to supply

Ossur Australia Pty Ltd - External lower-limb prosthesis adaptor

ARTG Identifier	308058
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	61229
GMDN Term	External lower-limb prosthesis adaptor
Intended Purpose	A component of an external lower-limb prosthetic intended to be used during customised fabrication of the prosthetic for attachment of the distal portion of the prosthetic to the proximal portion worn by the patient. It is used to facilitate fixation of the distal portion to a socket, socket adaptor attachment block, or other prosthetic component. Not intended to be in direct interaction with skin or body tissues. Applicable for low to moderate activity levels.

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. External lower-limb prosthesis adaptor

Product Specific Conditions

No specific conditions have been recorded against this entry.