



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 - Prosthesis, external, leg, partial foot

ARTG Identifier	308047
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	41533
GMDN Term	Prosthesis, external, leg, partial foot
Intended Purpose	An artificial replacement for part of the lower limb after amputation distal to the ankle joint. Toe prostheses are included. Includes a prosthetic device specifically designed for people with Chopart amputation as well as lisfranc, pirogoff, boyd and partial foot prostheses.

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, partial foot

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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