Australian Register of Therapeutic Goods Certificate

Issued to

Ossur Australia Pty Ltd

for approval to supply

Ossur Australia Pty Ltd - Prosthesis, external, arm, component, hand, passive

ARTG Identifier	309881
ARTG Start Date	28/09/2018
Product Category	Medical Device Included Class 1
GMDN	41078
GMDN Term	Prosthesis, external, arm, component, hand, passive
Intended Purpose	The device is intended to be used by patients with upper limb loss or deficiency. A livingskin passive functional device is one that typically offers some basic function and closely resembles the natural body part it is replacing.

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, arm, component, hand, passive

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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