



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, arm, component, hand, external powered, myopotential

ARTG Identifier	309511
ARTG Start Date	21/09/2018
Product Category	Medical Device Included Class 1
GMDN	41497
GMDN Term	Prosthesis, external, arm, component, hand, external powered, myopotential
Intended Purpose	A powered artificial substitute for a missing hand that may be attached to a natural arm or used as part of an upper-limb external prosthetic system, and is designed to replace the appearance and some of the function of the hand. The device moves as the result of a motor(s) that may be integral of proximally mounted with a mechanical link. The control of movement is achieved through amplified muscle action potentials from voluntary contracting muscle in the residual limb/trunk, transmitted via surface electrodes in the device that make contact with the skin, which turn on the motor to provide a function.

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, external powered, myopotential

Product Specific Conditions

No specific conditions have been recorded against this entry.