



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, partial hand

ARTG Identifier	309510
ARTG Start Date	21/09/2018
Product Category	Medical Device Included Class 1
GMDN	41486
GMDN Term	Prosthesis, external, arm, partial hand
Intended Purpose	An artificial replacement of part of the upper limb after amputation distal to the wrist joint. Finger prostheses are included. The device is intended to be used by patients with upper limb loss or deficiency. i-digits is a fully customized electronic device for people with missing fingers or partial hands. With i-digits™, anywhere from one to five missing fingers can be replaced with an individually powered prosthetic digits. Device has biosim control application which allows selection of different features, signal assessment, and training modes. Patient-triggered control is provided by either compact or remote electrodes. Silicone covering accessories are available which protect the digits from dust or water.

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, partial hand

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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