



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 - Electrical wrist prosthesis

<b>ARTG Identifier</b>	325342
<b>ARTG Start Date</b>	23/10/2019
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	41090
<b>GMDN Term</b>	Electrical wrist prosthesis
<b>Intended Purpose</b>	An artificial substitute for a missing wrist used as part of an upper-limb external prosthetic system and designed to restore some of the function of the joint. Enables pre-positioning of the wrist and hand in daily activities. Provides simultaneous rotation of the wrist on grip selection when used together with the i-Limb Quantum hand. Direct rotational control of the wrist is available.

Manufacturer Details	Address	Certificate number(s)
Ossur HF	Grjothals 1-5 Reykjavik , Iceland , 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. Electrical wrist prosthesis

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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