



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 - Lower-limb prosthesis tube

<b>ARTG Identifier</b>	308056
<b>ARTG Start Date</b>	10/08/2018
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	58823
<b>GMDN Term</b>	Lower-limb prosthesis tube
<b>Intended Purpose</b>	A device designed as a component of an external lower-limb prosthetic intended to replace the long section of a leg (e.g., from the knee or below the knee and down) and to join other limb components (e.g. to join a knee joint to an ankle joint or directly to a foot prosthetic). Some variants transfer load/impact and maintain structural integrity of a lower limb prosthetic, connecting and aligning parts of a prosthetic system.

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. Lower-limb prosthesis tube

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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