



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 - Single-axis manual lock knee prosthesis

ARTG Identifier	308057
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	58961
GMDN Term	Single-axis manual lock knee prosthesis
Intended Purpose	An artificial substitute for a transfemoral (above-the-knee) amputation designed as a component of an external lower-limb prosthetic to restore some of the appearance and/or function of the normal anatomy. Typically has no stance control (this means the amputee must use their own muscles to remain stable when standing) and uses the lock to compensate for lack of stance control; adjustable constant friction may be included to keep the leg from swinging forward too fast when moving to the next step. Intended for low active amputees, to be used during rehabilitation and as a permanent solution. Some variants intended to facilitate single cadence ambulation on level ground and small slopes, knees allow user to negotiate stairs and small obstacles as well as sitting and/or kneeling.

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. Single-axis manual lock knee prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.