



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 - Polycentric mechanical knee prosthesis

ARTG Identifier	308052
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	43795
GMDN Term	Polycentric mechanical knee prosthesis
Intended Purpose	An artificial substitute for a transfemoral (above-the-knee) and/or knee disarticulation amputation designed as a component of an external lower-limb prosthetic to restore some of the appearance and/or function of the normal anatomy. Some variants permit variable walking speed, enable variable or single cadence ambulation on level ground and small slopes. Includes polycentric (four-bar) mechanical prosthetic knees. Intended for use by above knee amputees with low or moderate to high activity level. Some variants intended to provide stability in stance throughout alignment with four bar geometry and provide adjustable extension and flexion swing rate. Some knees allow the user to negotiate stairs and small obstacles as well as sitting and/or kneeling. Some variants extend user activity to long distance running.

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. Polycentric mechanical knee prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.