



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 stabilizing knee prosthesis

ARTG Identifier	308055
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	58962
GMDN Term	Single-axis stabilizing 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. Incorporates adjustable swing and weight activated stance control. Some variants designed to offer high level of stability for low active users who typically use walking aids. Intended to facilitate single-speed walking on level ground and gentle slopes. Some variants provide stability and swing only mode is ideal for cycling, rowing and running and are intended to extend user's activity by providing stability in stance. Some variants are intended for above the knee amputees with moderate to high activity level and are intended to enable variable cadence ambulation on level ground and small slopes, stability in stance through a load depending brake and provide adjustable extension and flexion swing rate.

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 stabilizing knee prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.

