



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	324606
ARTG Start Date	9/10/2019
Product Category	Medical Device Included Class IIa
GMDN	58962
GMDN Term	Single-axis stabilizing knee prosthesis
Intended Purpose	To provide mobility to the lower limb amputee. Sensors within the prosthetic knee prosthesis provide real-time information during the gait cycle. The information is utilised to control joint resistance by activating a magnetorheological actuator.

Manufacturer Details	Address	Certificate number(s)
Ossur HF	Grjothals 1-5 Reykjavik , Iceland , 110 Iceland	DV-2019-MC-14278-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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.

Therapeutic Goods Administration
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