



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 - Multi-axis foot prosthesis

ARTG Identifier	308051
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	43571
GMDN Term	Multi-axis foot prosthesis
Intended Purpose	An artificial substitute for a foot designed as a component of an external lower-limb prosthetic to restore some of the appearance and/or function of the normal anatomy. Targeted for users with lower extremity amputation physically fit for using a prosthetic to replace the function of an amputated lower limb. Intended for transfemoral, knee disarticulation and transtibial users, unilateral and bilateral. Intended for low to moderately active amputees specially designed to provide fluid, natural walking motion in a variety of terrains. Constructed to permit ankle movement in three planes to accommodate uneven terrain and to absorb torques that would otherwise produce shearing forces on the residual limb.

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. Multi-axis foot prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.