



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 - Dynamic-response foot prosthesis

ARTG Identifier	308050
ARTG Start Date	10/08/2018
Product Category	Medical Device Included Class 1
GMDN	43569
GMDN Term	Dynamic-response 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. Replaces function or aesthetics of a missing limb. Enables the store and release of energy during the walking cycle to provide a sense of push-off and a more normal gait range. Intended for an active and responsive patient to help increase activity level (e.g., vary walking speed, change direction quickly, walk long distances). Intended for transfemoral, knee disarticulation and trans-tibial users, unilateral and bilateral. To be used by highly active or low to moderately active patients. Some variants can be used as part of a system with a socket, shank and foot. Helps more natural gait, protects the sound limb and remaining joints of the amputated limb from excessive shock.

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. Dynamic-response foot prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.