



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Ossur Australia Pty Ltd

for approval to supply

Ossur Australia Pty Ltd - Mechatronic external ankle-foot prosthesis

ARTG Identifier	411042
ARTG Start Date	22/06/2023
Product Category	Medical Device Included Class 1
GMDN	64725
GMDN Term	Mechatronic external ankle-foot prosthesis
Intended Purpose	The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower 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. Mechatronic external ankle-foot prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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