

### 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 - Mechanical-resistance external ankle-foot prosthesis

**ARTG Identifier** 461986

**ARTG Start Date** 5/09/2024

**Product Category** Medical Device Included Class 1

**GMDN** 64723

**GMDN Term** Mechanical-resistance external ankle-foot prosthesis

**Intended Purpose** External lower limb devices are designed to replace one or more

functions of the biologic human (adult and children) foot or ankle-foot

system.

Manufacturer Details	Address	Certificate number(s)
College Park Industries Inc	27955 College Park Drive Warren , MI , 48088- 4877 United States Of America	

#### **ARTG Standard Conditions**

The above Medical Device Included Class 1 has been entered on the Register subject to the following

- 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. Mechanical-resistance external ankle-foot prosthesis

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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