

### 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 - Hydraulic/pneumatic external knee prosthesis

**ARTG Identifier** 461978

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

**Product Category** Medical Device Included Class 1

**GMDN** 64719

**GMDN Term** Hydraulic/pneumatic external knee prosthesis

**Intended Purpose** This device is intended for transfemoral amputees, is a prosthetic device

designed to restore some function of an anatomical knee joint.

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 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. Hydraulic/pneumatic external knee prosthesis

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 461978 ARTG Start Date: 5/09/2024