



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 knee prosthesis

ARTG Identifier	463488
ARTG Start Date	1/10/2024 11:00:00 PM
Product Category	Medical Device Included Class 1
GMDN	64721
GMDN Term	Mechatronic external knee prosthesis
Intended Purpose	The product is intended for transfemoral amputees as a prosthetic medical 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. Mechatronic external knee prosthesis

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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