

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 - Passive shoulder prosthesis

ARTG Identifier 474973

ARTG Start Date 3/01/2025

Product Category Medical Device Included Class 1

GMDN 41102

GMDN Term Passive shoulder prosthesis

Intended Purpose The device is a prosthetic shoulder joint intended to replace one or more

functions of the biological human shoulder.

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. Passive shoulder 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: 474973 ARTG Start Date: 3/01/2025