

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Pod Active Pty Ltd - Orthosis, leg, knee, unit 373290

ARTG entry for Medical Device Included Class 1

Sponsor Pod Active Pty Ltd

Postal Address PO Box 2268, Geelong, VIC, 3220

23/08/2021 ARTG Start Date

Product Category Medical Device Class 1

Status Active

Medical Devices Approval Area

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.

Manufacturers

Name **Address**

Pod Active Pty Ltd Level 3

> 115 Myers Street Geelong, VIC, 3220

Australia

Products

1 . Orthosis, leg, knee, unit

Effective Date 23/08/2021 **Product Type** Single Device Product

GMDN 41065 Orthosis, leg, knee, unit

Intended Purpose The device provides additional support to knee joints and may function in the following modes:

- Prophylactic where it is intended to prevent and/or reduce the severity of injuries to the knee (typically prior to injury);
- · Functional where it is intended to provide support and stability to previously injured knees and sometimes following surgery; · Rehabilitative where it is intended to provide support and stability and limit potentially harmful or injurious knee movement to the

knee joint following recent injury or surgery.

Specific Conditions

No Specific Conditions included on Record

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