



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 403914 Ossur Australia Pty Ltd - Finger/thumb prosthesis

ARTG entry for Medical Device Included Class 1
Sponsor Ossur Australia Pty Ltd
Postal Address 26 Ross Street, NORTH PARRAMATTA, NSW, 2151
Australia
ARTG Start Date 30/01/2023
Product Category Medical Device Class 1
Status Active
Approval Area Medical Devices

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
Naked Prosthetics	408 Olympia Ave NE Olympia, WA, 98501 United States Of America

Products

1 . Finger/thumb prosthesis

Product Type	Single Device Product	Effective Date	30/01/2023
GMDN	16094 Finger/thumb prosthesis		
Intended Purpose	Finger/thumb prosthetic device. The device is intended to be used by patients with partial finger/thumb amputations, or patients with complete finger amputations or congenital anomalies. Prosthesis may include body-interface accessories such as sockets, rings, straps, and other soft goods, external gripping accessories such as cosmetic fairings and grip pads, and internal mechanical components for power delivery, such as frames and fastening hardware to enable functional use of the device.		

Specific Conditions

No Specific Conditions included on Record

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