



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 197169 Ossur Australia Pty Ltd - Orthosis, footwear, orthopaedic, shoe, ready-made

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 4/05/2012
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
Darco International Inc	810 Memorial Boulevard Huntington, West Virginia, 25701 United States Of America

Products

1. Orthosis, footwear, orthopaedic, shoe, ready-made

Product Type	Single Device Product	Effective date	4/05/2012
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GMDN 31041 Orthosis, footwear, orthopaedic, shoe, ready-made

Intended purpose Post operative style shoe to offload foot

Specific Conditions

No Specific Conditions included on Record

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