



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 135046 Ossur Australia Pty Ltd - Orthosis, leg, ankle/foot, unit

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 19/02/2007
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

Ossur Hf

Address

27412-A Laguna Hills Drive
 ALISO VIEJO, CALIFORNIA, 92656
 United States Of America

Products

1. Orthosis, leg, ankle/foot, unit

Product Type	Single Device Product	Effective date	19/02/2007
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GMDN 36206 Orthosis, leg, ankle/foot, unit

Intended purpose An orthosis that encompassess the ankle joint and the whole or part of the foot. This device is body worn.

Specific Conditions

No Specific Conditions included on Record

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