



## Medical Device Details

Sponsor: Ossur New Zealand Limited  
6/80 Westpoint Drive  
Hobsonville  
Auckland  
New Zealand

WAND Reference: 211222-WAND-6Y6BCV

Sponsors Own Reference: Orthosis, leg, ankle/foot, unit

GMDN: Ankle/foot orthosis [36206]

Class: I

Intended Purpose: An orthosis that encompasses the ankle joint and the whole or part of the foot. This device is body worn.

Manufacturer: Ossur HF Grjothals 5  
Reykjavik  
Iceland

ARTG ID: 135046

- > The device is supplied unsterilised.
- > The device is not intended to be invasive.
- > The device is not intended for single use.
- > The device is not an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.
- > The device does not contain human blood or its components.
- > The device consists of: Single product
- > The device does not contain material or ingredients of animal origin.
- > The device is not medicated.
- > The device is not formulated.
- > The product does not contain a medicine that has consent for marketing in New Zealand.
- > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active