



Medical Device Details

Sponsor: Ossur New Zealand Limited
Regus, 6 Clayton Street
Newmarket
Auckland
New Zealand

WAND Reference: 211223-WAND-6Y6F7N

Sponsors Own Reference: Splint, mouldable, vacuum

GMDN: Vacuum mouldable splint [35358]

Class: I

Intended Purpose: The device is intended to immobilize, protect and control post-operative edema in the residual limb.

Manufacturer: Ossur HF Grjothals 5
Reykjavik
Iceland

ARTG ID: 308046

- > 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