

## **Medical Device Details**

Ossur New Zealand Limited

6/80 Westpoint Drive

Sponsor: Hobsonville

Auckland New Zealand

WAND Reference: 211223-WAND-6Y6F5T

Sponsors Own Reference: Orthosis, arm, shoulder/elbow, unit

GMDN: Elbow orthosis [41053]

Class: I

Intended Purpose: Elbow Orthosis

Ossur HF Grjothals 5

Manufacturer: Reykjavik

Iceland

ARTG ID: 165446

- > 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