

Medical Device Details

Ossur New Zealand Limited

6/80 Westpoint Drive

Sponsor: Hobsonville

Auckland New Zealand

WAND Reference: 230623-WAND-71FOQ2

Sponsors Own Reference: Proprio - Class I

GMDN: Mechatronic external ankle-foot prosthesis [64725]

Class: I

Intended Purpose:

The device is intended as a part of a prosthetic system that replaces the foot and ankle function of a missing lower

limb.

Ossur HF Grjothals 5

Manufacturer: Reykjavik

Iceland

ARTG ID: 411042

> The device is supplied unsterilised.

- > The device is not intended to be invasive.
- > The device is not intended for single use.
- > The device is 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