



Medical Device Details

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

WAND Reference: 211223-WAND-6Y6IMS

Sponsors Own Reference: Single-axis manual lock knee prosthesis

GMDN: Mechanical-resistance external knee prosthesis [64718]

Class: I

Intended Purpose: The device is intended as a part of a prosthetic system that replaces knee function of a missing lower limb

Manufacturer: Ossur HF Grjothals 5
Reykjavik
Iceland

ARTG ID: 308057

- > 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