



Medical Device Details

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

WAND Reference: 211223-WAND-6Y6IPT

Sponsors Own Reference: Transfemoral prosthesis socket

GMDN: External limb prosthesis socket shell fabrication material [64714]

Class: I

Intended Purpose: The device is a pre-assembled, size adjustable socket intended as a part of a prosthetic system that replaces a missing lower limb

Manufacturer: Ossur HF Grjothals 5
Reykjavik
Iceland

ARTG ID: 325341

- › 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