



## Medical Device Details

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

WAND Reference: 221110-WAND-703IQ3

Sponsors Own Reference: Anatomical Concepts - PRAFO

GMDN: Leg self-moulding splint system [43588]

Class: I

Intended Purpose: AIDS FOR DISABLED PERSONS-ORTHOSES/ORTHOTIC COMPONENTS  
Anatomical Concepts Inc 1399 E Western Reserve Road  
Youngstown

Manufacturer: Ohio  
United States

### ARTG ID:

- › 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