



Medical Device Details

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

WAND Reference: 221110-WAND-703IM5

Sponsors Own Reference: DARCO - Orthowedge

GMDN: Orthotic shoe, ready-made [31041]

Class: I

Intended Purpose: Reduce weight bearing pressure on the forefoot which promotes faster healing when forefoot wounds or ulcerations are present.

Manufacturer: Darco International Inc 1327 7th Avenue
Huntington
West Virginia
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