



Medical Device Details

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

WAND Reference: 221110-WAND-703IQR

Sponsors Own Reference: HTFO - Spinal Brace

GMDN: Lumbar spine orthosis [33031]

Class: I

Intended Purpose: "This is an externally worn rigid frame device that is considered as a Thoracolumosacral (High Taylor) or Lumbosacral (Low Taylor) brace depending on the regional treatment requirements of the patient. It is intended to be used to encompass the thoracic and / or lumbar spine region of the trunk to support or immobilize deformities, fractures, sprains, or strains of the spine. This is a single use device."

Manufacturer: Head to Foot Orthotics 39 Centre Way
Croydon South
Victoria
Australia

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