



## Medical Device Details

Sponsor: CARSL Consulting  
P O Box 766  
Hastings  
New Zealand

WAND Reference: 190412-WAND-6SB2Q3

Sponsors Own Reference: Precise Medical Supplies - Su-Por prosthesis, internal,ear/nose/throat, synthetic

GMDN: Polyethylene craniofacial tissue reconstructive material [33310]

Class: Ila

Intended Purpose: Intended for non-weight bearing applications of craniofacial reconstruction/cosmetic surgery, repair of craniofacial trauma and for the augmentation or restoration of contour in the craniomaxillofacial skeleton.

Manufacturer: Poriferous LLC 535 Pine Road  
Newnan  
Georgia  
United States

ARTG ID: 267380

- ▶ The device is supplied sterile.
  - ▶ Sterilisation method: Ethylene oxide
- ▶ The device is intended to be invasive.
- ▶ The device is 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