



Medical Device Details

Sponsor: Mango Medtech Limited
12 Madden Street
Auckland
New Zealand

WAND Reference: 210830-WAND-6XHP5B

Sponsors Own Reference: EDG Ortho Depth Gauge

GMDN: Surgical depth gauge, single-use [58796]

Class: IIa

Intended Purpose: Single use surgical depth gauge designed for use during orthopaedic surgical procedures.
EDGE Surgical Inc 222 W Merchandise Mart Plazz, Suite 1230
Chicago
Illinois
United States

Manufacturer:

ARTG ID:

- ☑ > 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