



Medical Device Details

Sponsor: AA-Med NZ Ltd
6 Church Lane
Point Howard
Lower Hutt
Wellington
NEW ZEALAND

WAND Reference: 161121-WAND-6N496I

Sponsors Own Reference: KegelCore

GMDN: Pelvic floor muscle exerciser [46624]

Class: I

Intended Purpose: The KegelCore is a pelvic floor muscle toner and exerciser. It is designed to treat mild to moderate stress, mixed, or urge urinary incontinence in women through the strengthening and toning of dysfunctional pelvic floor muscles caused by hypo/hypertonicity and is intended for independent at-home use.

Manufacturer: Standard Innovation Corporation Suite 330, 1130 Morrison Drive
Ottawa
Ontario Province
Canada

ARTG ID: 279622

- › The device is supplied unsterilised.
- › The device is intended to be invasive.
- › The device is not intended for single use.
- › The device is 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