

## Medical Device Details

Sponsor: AA-Med NZ Ltd  
Level 7, 54 Gill Street  
New Plymouth 4310  
New Zealand

WAND Reference: 200904-WAND-6VCNF1

Sponsors Own Reference: DermaSensor

GMDN: Dermatological elastic scattering spectroscopy probe [64023]

Class: I

Intended Purpose: The DermaSensor device is indicated for use as an objective tool to assist medical professionals in evaluating skin lesions. The DermaSensor device is intended to assist the user in deciding whether skin lesions require further clinical care and is not intended to be used for direct diagnosis of skin cancer.

Manufacturer: DermaSensor Inc 80 S W 8th Street, Suite 2000  
Miami  
Florida 33130  
United States

ARTG ID: 341101

- › The device is supplied unsterilised.
- › The device is not 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