

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 151788 Niagara Australia Pty Ltd - Massager, electrical

ARTG entry for Medical Device Included Class IIa

Sponsor Niagara Australia Pty Ltd

Postal Address 29 Resource Street, Parkinson, NSW, 4115

Australia

ARTG Start Date 22/04/2008

Product category Medical Device Class IIa

Status Active

Approval area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name Address

CT Healthcare Pty Ltd T/A Niagara Therapy 29 Resource Street

PARKINSON, QLD, 4115

Australia

Products

1. Massager, electrical

Product Type Single Device Product Effective date 22/04/2008

GMDN 36560 Massager, electrical

Intended purpose The device provides a type of therapeutic massage called cycloid vibration therapy (CVT). The device is

hand held and is in the form of a rectangular pad used to apply CVT to all parts of the body. This device may reduce excess interstitial oedema fluid whether the cause is lymphatic or vascular; may assist in the reduction of musculoskeletal pain; may increase local area blood flow; and may assist in the treatment of wounds, cellulitis and pressure ulcers where an improvement in local circulation is a factor and may assist

in joint mobilisation.

Specific Conditions

No Specific Conditions included on Record

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