



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 218614 Aero Healthcare - Burn wrap

ARTG entry for Medical Device Included Class Is

Sponsor Aero Healthcare

Postal Address PO Box 1635, ARMIDALE, NSW, 2350
Australia

ARTG Start Date 17/12/2013

Product Category Medical Device Class Is

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
Aero Health Aust Pty Ltd T/A Aero Healthcare (Australia)	63 Seaton Street ARMIDALE, NSW, 2350 Australia

Products

1 . Burn wrap

Product Type	Effective Date
Single Device Product	17/12/2013

GMDN 36093 Burn wrap

Intended Purpose A sterile, trauma covering used to maintain the stability of a burn patient en route to a burn centre or hospital. The device is intended to be applied at the emergency site and is used to prevent burn progression, minimize trauma, and provide protection against contamination. This device may be of various materials and sizes. This is a single use device.

Specific Conditions

No Specific Conditions included on Record

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