



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 221543 Aero Healthcare - Wound hydrogel dressing, sterile

ARTG entry for Medical Device Included Class IIa

Sponsor Aero Healthcare

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

ARTG Start Date 21/03/2014

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

Products

1 . Wound hydrogel dressing, sterile

Product Type	Effective Date
Single Device Product	21/03/2014

GMDN 47764 Wound hydrogel dressing, sterile

Intended Purpose A sterile wound covering impregnated with gel for first aid treatment of minor burns. The device is intended to cool the burn and soothe pain. It also acts a mechanical barrier to help protect the wound from infection. It may also absorb exudates in wounds that are minimally to moderately exudative. This is a single-use device.

Specific Conditions

No Specific Conditions included on Record

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