



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 427910 Aero Healthcare - Burn gel, sterile

ARTG entry for Medical Device Included Class IIa

Sponsor Aero Healthcare

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

ARTG Start Date 15/11/2023

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 . Burn gel, sterile

Product Type	Single Device Product	Effective Date	15/11/2023
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GMDN 47694 Burn gel, sterile

Intended Purpose A non-sterile gel intended to be applied topically to a minor burn or sunburn. It is designed to protect against infection, minimize trauma and skin damage, provide pain relief, moisten and cool the burn area and prevent burn progression. It is available in tube form, and is used by emergency services but may also be used in the home.

Specific Conditions

No Specific Conditions included on Record

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