

## **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

### **Aero Healthcare**

for approval to supply

# Aero Healthcare - Skin-cleaning wipe, non-sterile

ARTG Identifier 277597

ARTG Start Date 8/07/2016

Product Category Medical Device Included Class 1

**GMDN** 61694

**GMDN Term** Skin-cleaning wipe, non-sterile

Intended Purpose non-sterile device consisting of an absorbent fabric pre-soaked in a

liquid solution (e.g. Povidone Iodine)intended for cleaning a localized body surface before a procedure or device application, and/or to maintain skin hygiene. It is commonly known as a wet wipe and is normally available [non-prescription]over-the-counter (OTC) for use in

the home or healthcare facility. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Aero Healthcare Aust Pty Ltd T/A Aero Healthcare	63 Seaton Street ARMIDALE , NSW , 2 350 Australia	

#### **ARTG Standard Conditions**

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

#### **Products Covered by This Entry**

1. Skin-cleaning wipe, non-sterile

### **Product Specific Conditions**

· No specific conditions have been recorded against this entry.

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