



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 452885 Aimwell Pty Ltd - AYO HC Healthcare Reusable Respirator - Respirator filter/cartridge, particulates

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** Aimwell Pty Ltd  
**Postal Address** Suite 205 56 Delhi Road, Macquarie Park, NSW, 2113  
Australia  
**ARTG Start Date** 19/06/2024  
**Product Category** Medical Device Class 1  
**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
Aimwell Pty Ltd	Suite 205 56 Delhi Road Macquarie Park, NSW, 2113 Australia

### Products

#### 1 . AYO HC Healthcare Reusable Respirator - Respirator filter/cartridge, particulates

Product Type	Medical device system	Effective Date	19/06/2024
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**GMDN** 64966 Respirator filter/cartridge, particulates

**Intended Purpose**

- to prevent the transmission of airborne diseases between people;
- for therapeutic use such as for surgical, clinical, medical use, or use in other health services;
- for general public respiratory protection from air pollution, pollen, bushfires, etc.

Note: This is the filer element to be used with the respirator body applied separately to this application.

### Specific Conditions

No Specific Conditions included on Record

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Public Summary