



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

## Public Summary

|                                |  |   |
|--------------------------------|--|---|
| <b>Summary for ARTG Entry:</b> | 443770   | Livingstone International Pty Ltd - Public respirator, single-use |
| <b>ARTG entry for</b>          | Medical Device Included Class 1  |   |
| <b>Sponsor</b>                 | Livingstone International Pty Ltd  |   |
| <b>Postal Address</b>          | Suite 1 Level 9 Building 3, 189 O Riordan Street, Mascot, NSW, 2020<br>Australia |   |
| <b>ARTG Start Date</b>         | 14/03/2024   |   |
| <b>Product Category</b>        | Medical Device Class 1   |   |
| <b>Status</b>                  | Active   |   |
| <b>Approval Area</b>           | 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   |
|----------------------------|---|
| 3A Medical Products Co Ltd | Yu An Industrial Park Yu An District Liu An<br>, Anhui, 237100<br>China |

### Products

#### 1 . Public respirator, single-use

|                         |   |                       |            |
|-------------------------|---|-----------------------|------------|
| <b>Product Type</b>     | Single Device Product   | <b>Effective Date</b> | 14/03/2024 |
| <b>GMDN</b>             | 57793 Public respirator, single-use   |                       |            |
| <b>Intended Purpose</b> | A form-shaped filtering mask designed to be placed over the nose and mouth of the wearer to protect them from exposure to large particles and small particles. It is designed as an aid in the prevention of transmission of disease via respiratory passages. This is a single use device. |                       |            |

### Specific Conditions

No Specific Conditions included on Record

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