



# Medical Device Application

**ARTG No : 421872**

## Class 1 Status: Approved

### Application Change history

#### Application Progress Date

Date received: 13/09/2023

#### Review Information

Review flag:

Auto review required: No

#### Device Product Characteristics

Is the device, or any form of the device, supplied sterile: No  
 Is the device intended to be invasive: No  
 Is the device, or any form of the device, intended for single use: No  
 Is the device an active device: No  
 Does the device contain material or ingredients of microbial origin: No  
 Does the device contain material or ingredients of recombinant origin: No  
 Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No  
 Does the device contain material or ingredients of Human Origin: No  
 Does the device consist of: Single product only  
 Does the device contain material or ingredients of Animal Origin rendered non-viable: No  
 Is the device medicated: No  
 Does the product contain a medicine that is supplied separately in the Australian Market: No  
 Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No  
 Is the device software or does it incorporate software? No

#### Application Summary

Application ID: DV-2023-DA-25639-1  
 Submission ID: DA-2023-07356-1  
 Sponsor's own reference: ECP HEALTH  
 Application for: Medical Device - Included (Export Only)  
 Are you applying for a medical device production system? No  
 Sponsor name: Vicki Partridge Pty Ltd  
 Sponsor ID: s47G  
 Agent name: s47G

|                                                             |     |
|-------------------------------------------------------------|-----|
| Contact details:                                            | s22 |
| Contact email:                                              | s22 |
| Is this application supported by EU MDR/IVDR certification? | No  |

### Manufacturer Information

|                    |                                                                                                                                                                                                                                         |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer name: | Shenzhen JWEI Electronics Co Ltd (China)[77950]                                                                                                                                                                                         |
| GMDN code:         | Nebulizer, heated[12716]                                                                                                                                                                                                                |
| GMDN description:  | A device used to produce warmed aerosol mist (water vapour or droplets) to deliver medication into the lungs with oxygen or compressed air therapy. It may consist of a reservoir, a heating element, a compressor and a nebulizer jet. |
| Intended purpose:  | A device used to produce warmed aerosol mist (water vapour or droplets) to deliver medication into the lungs with oxygen or compressed air therapy.                                                                                     |

### Device Category Terms

|                    |                                                |
|--------------------|------------------------------------------------|
| Device category 1: | Anaesthetic and respiratory devices            |
| Device category 2: | Assistive products for persons with disability |

### Attached Documentation

 Declaration of Conformity - NEW\_Class\_1\_DoC signed.pdf

### History

15/09/2023 8:01:38 AM Approved.

Review Completed - Accepted, 15/09/2023)

| Record         | Date       |
|----------------|------------|
| Fee:           | 92         |
| Date Paid:     | 14/09/2023 |
| Date Decision: | 15/09/2023 |

| Start Dates          | Finish Dates | Working Days                      |
|----------------------|--------------|-----------------------------------|
| Application Received | 13/09/2023   | Payment Received 14/09/2023 1     |
| Payment Received     | 14/09/2023   | Application Decision 15/09/2023 2 |

Total Working  
Days

3

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# Manufacturer's Declaration of Conformity for Class I non-sterile, non-measuring or Class 1 in vitro diagnostic (IVD) medical devices

This Declaration of Conformity (DoC) is required under clause 6.6 (for single devices or kinds of devices) of Schedule 3 of the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Regulations).

An Australian DoC must be completed by the manufacturer of a Class I non-sterile, non-measuring device or a Class 1 in vitro diagnostic (IVD) device.

For more information on how to complete this DoC refer to [Guidance for Declaration of Conformity for Class I non-sterile non-measuring and Class 1 in vitro diagnostic \(IVD\) medical devices](#).

This document can be:

- used for single or multiple devices.
- filled out by hand and then scanned and submitted, or filled out electronically.

## Manufacturer's details

|                                 |                                                                                                                                       |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer's name             | Shenzhen JWEI Electronics Co., Ltd.                                                                                                   |
| Manufacturer's business address | Floor 2, 3, 4, Area 1, Building 14, Gonghe Hengmingzhu Tech Industrial Park, Shajing Town, Baoan District, Shenzhen, Guangdong, China |

## Classification type

Specify if your device is:

- ☒ Class I non-sterile, non-measuring device
- ☐ Class 1 in vitro diagnostic (IVD) medical device

## GMDN code and term

Select the most appropriate Global Medical Device Nomenclature (GMDN) code for this product. GMDN codes and terms are a system of internationally agreed generic descriptors that are used to identify all medical device products. Class 1 IVDs require the use of a level 1 collective term (CT). Please refer to the following link for guidance regarding an appropriate CT for the kind of device: [The use of GMDN codes for IVD medical devices in Australia](#).

GMDN codes are generated by the [GMDN Agency](#).

The GMDN code tables are available on [TGA Business Services \(TBS\)](#).

|            |        |
|------------|--------|
| GMDN codes | 112716 |
|------------|--------|

**Standards applied to the device(s)**

List any standards used in the manufacturing of the device, including:

- International Standards (ISO)
- Australian Standards (AS)
- Conformity Assessment Standard Orders (CASO)
- Medical Device Standard Orders (MDSO)

|           |                        |
|-----------|------------------------|
| Standards | ISO9001, ISO45001, GMP |
|-----------|------------------------|

**Name of medical device(s) / IVD(s)**

Identify the specific device/s this form relates to for example, the name of the device or model

|                                  |       |
|----------------------------------|-------|
| Name of medical device(s)/IVD(s) | SAABI |
|----------------------------------|-------|

numbers of the device and any variants that are being manufactured for supply in Australia.

**This declaration is being made under clause 6.6 of Schedule 3 to the Regulations for a Class I non-sterile, non-measuring device or Class 1 IVD medical device.**

**By signing this form you are agreeing that:**

- You have reviewed the Declaration of Conformity procedures under Part 6 of Schedule 3 of the Regulations and the device complies with the applicable provisions of those procedures.
- The device complies with the relevant essential principles set out in Schedule 1 to the Regulations.
- The device complies with the applicable provisions of the classification rules set out in Schedule 2 to the Regulations.
- You will update the technical documentation when any changes are made in relation to the device.

**Important note**

Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the *Criminal Code Act 1995*.

|           |     |      |               |
|-----------|-----|------|---------------|
| Name      | s22 |      |               |
| Title     | s22 |      |               |
| Signature | s22 | Date | Sep. 11. 2023 |



Australian Government  
Department of Health, Disability and Ageing  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**SAABI AU Pty Ltd**

for approval to supply

**SAABI AU Pty Ltd - Nebulizer, heated**

|                         |                                                                                                                                                     |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ARTG Identifier</b>  | 421872                                                                                                                                              |
| <b>ARTG Start Date</b>  | 15/09/2023                                                                                                                                          |
| <b>Export Names</b>     | SAABI                                                                                                                                               |
| <b>Product Category</b> | Medical Device Included (Export Only) Class 1                                                                                                       |
| <b>GMDN</b>             | 12716                                                                                                                                               |
| <b>GMDN Term</b>        | Nebulizer, heated                                                                                                                                   |
| <b>Intended Purpose</b> | A device used to produce warmed aerosol mist (water vapour or droplets) to deliver medication into the lungs with oxygen or compressed air therapy. |

| Manufacturer Details             | Address                                                                                                                                                        | Certificate number(s) |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Shenzhen JWEI Electronics Co Ltd | GMP Workshop 3F Block 14<br>Hengmingzhu Technology<br>Industrial Park Gonghe<br>Shajin Street Baoan District<br>Shenzhen City, Guangdong<br>Province,<br>China |                       |

## ARTG Standard Conditions

The above Medical Device Included (Export Only) 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. Nebulizer, heated

## Product Specific Conditions

No specific conditions have been recorded against this entry.