

### **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

### Shengquan (Australia) High-Tech Pty Ltd

for approval to supply

## Shengquan (Australia) High-Tech Pty Ltd - Mask, surgical, single use

ARTG Identifier 340228

ARTG Start Date 27/07/2020

Product Category Medical Device Included Class 1

**GMDN** 35177

**GMDN Term** Mask, surgical, single use

Intended Purpose This is face masks produced by Shandong Shengguan New Materials

Co Ltd. The product is a disposable medical device made from Fabric and other materials placed over the nose and mouth to prevent the

transmission of airborne organisms.

Manufacturer Details	Address	Certificate number(s)
Shandong Shengquan New Materials Co Ltd	Diaozhen Industrial Development Zone Zhangqiu , Shandong , China	

#### **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. Mask, surgical, single use

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 340228 ARTG Start Date: 27/07/2020