

## **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

### PROMOTEK PTY LTD

for approval to supply

# PROMOTEK PTY LTD - Mask, surgical, single use

ARTG Identifier 335205

**ARTG Start date** 25/04/2020

Product Category Medical Device Included Class 1

**GMDN** 35177

GMDN Term Mask, surgical, single use

Intended Purpose Disposable 3ply mask supplied as non-sterile for personal protection

use.

Manufacturer Details	Address	Certificate number(s)
XIAMEN PROBTAIN NONWOVEN INC	No 6 Ji'an Road TongAn District Xiamen City Fujian Province , China, 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: 335205 ARTG Start Date: 25/04/2020