

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Dane Taylor Technologies Pty Ltd

for approval to supply

Dane Taylor Technologies Pty Ltd - Fair Air mask - Airway protection face mask

ARTG Identifier 336200

ARTG Start Date 12/05/2020

Product Category Medical Device Included Class 1

GMDN 18094

GMDN Term Airway protection face mask
Intended Purpose Airway protection face mask

A flexible, form-shaped device that is placed over the nose and mouth to provide respiratory protection. It prevents the wearer from inhaling dusts, mists, and other airborne particles, including tuberculosis (TB) bacteria, present in the environment. It is made of natural materials that produce a soft, flexible mask that will create an airtight seal against the patient's face. The device consists of a filter held in a headstrap. One size fits all. This is a washable and reusable device that may be

sterilised.

CSIRO tests show that it removes 99.94% of 0.3 micron and 100% of 0.7 micron and larger particulates. (compared to ~94% for P2 masks) Easy to breathe and talk through. Comfortable to wear for long periods of time. Quick to put on/ remove. Also works effectively for wearers with facial hair. Highly fire resistant (was designed as mask for bushfire fighters).

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Manufacturer Details	Address	Certificate number(s)
Dane Taylor Technologies Pty Ltd	113 Clarke Street Benalla , VIC , 3672 Australia	

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. Fair Air mask - Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration

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Phone: 1800 020 653 Email: info@tga.gov.au ARTG Start Date: 12/05/2020