



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

H & S Trading Pty Ltd

for approval to supply

H & S Trading Pty Ltd - Mask, surgical, single use

ARTG Identifier	341388
ARTG Start Date	12/08/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a healthcare worker to permit normal breathing while protecting the patient and wearer from the transfer of large particles (e.g., blood, body fluids, and airborne particulate materials) during medical procedures and patient examination; it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or transparent face/eye visor intended to protect the upper face/eyes from debris/fluid. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
Fujian Hongle Technology Co Ltd	No 164 South Area Junbian Village Yonghe Town Jinjiang Quanzhou City , Fujian Province , 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.