



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Sleepcraft Distributors Pty Ltd

for approval to supply

Sleepcraft Distributors Pty Ltd - Mask, surgical, single use

ARTG Identifier	333076
ARTG Start date	1/04/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	<p>The intended use of this product is supply the Health Services Victoria urgently for the COVID-19 crisis.</p> <p>Surgical Face Masks Type II (Non-Sterile) Protecting healthcare staff and patients from infectious diseases Type I - EN14683 Standard, features include:</p> <ul style="list-style-type: none">·Pleat style with ear loops·Protective three-layer construction <p>Medical face masks help prevent large particles expelled by the wearer from reaching the patient or work environment.</p> <p>Type I - EN14683 masks are appropriate for situations where exposure to blood and/or bodily fluids from the patient or work environment is not a risk for the healthcare worker.</p>

Manufacturer Details	Address	Certificate number(s)
Wuxi JHT Group Co Ltd	66 Huichang Road Huishan Industrial Park Wuxi, Jiangsu, 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.