



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Zenpharm Pty Ltd

for approval to supply

Zenpharm Pty Ltd - Mask, surgical, single use

ARTG Identifier	332554
ARTG Start date	26/03/2020
Product Category	Medical Device Included Class 1
GMDN	35177
GMDN Term	Mask, surgical, single use
Intended Purpose	Endeavour Surgical Mask holds both CE (EN 14683:2005) and FDA approved certificates. This product is fluid resistance and has a filter efficiency level of 98% against bacteria. User Directions: 1. Mask must be replaced if damaged, breathing becomes difficult, or contaminated with blood or body fluid. 2. Do not reuse mask. Discard after every use. Dispose with care.

Manufacturer Details	Address	Certificate number(s)
FuJian YingDaWo Medical Technology Co Ltd	1/F Plant No 30 Tianshui Road Gaishan Town Cangshan District, Fuzhou Fujian, 350005 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
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