

# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 341916 Sweet Memories Promotional Gifts Pty Ltd - Mask, surgical, single use

ARTG entry for Medical Device Included Class 1

**Sponsor** Sweet Memories Promotional Gifts Pty Ltd

Postal Address Unit 11 595 Princes Highway, Tempe, NSW, 2044

Australia

ARTG Start Date 21/08/2020

Product Category Medical Device Class 1

Status Active

Approval Area Medical Devices

### 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 (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.

#### Manufacturers

Name Address

Audress

Ningbo Hpdove Dental Instruments Co Ltd No 588 Xiaolin Road Xiaolin Town

Cixi City, Zhejiang Province,

China

#### **Products**

### 1. Mask, surgical, single use

Product Type Single Device Product Effective Date 21/08/2020

**GMDN** 35177 Mask, surgical, single use

Intended Purpose Medical device(s): 3 ply disposable Mask

Classification: Class I non-sterile, non-measuring GMDN code and term: 35177 Mask

Scope of application: disposable medical mask

For All Class I

# Specific Conditions

No Specific Conditions included on Record

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