

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Record Summary	399056	Precise Medical Supplies Pty Ltd - Pump, roller
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Sponsor Precise Medical Supplies Pty Ltd

Medical Device Therapeutic Type Included Class IIa **Product Category**

9/11/2022 ARTG Start Date

Postal Address PO Box 421, Paddington, NSW, 2021

Australia

Billing Address PO Box 421, Paddington, NSW, 2021

Australia

Product Type Medical Device - Class IIa - Included

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 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.

Manufacturers

Name	Address	Certificate number(s)
HK Surgical Incorporated	1271 Puerta Del Sol	DV-2022-MC-19918-1

San Clemente, California, 92673 United States Of America

Products

1 . Pump, roller

Product Type	Single Device Product	Status	Current
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Effective Date 9/11/2022

GMDN 36664 Pump, roller Not included on record **Functional**

Description

Intended Purpose To deliver fluid subcutaneously, primarily saline during liposuction, into surgically accessed body cavities. It can also be used to

subcutaneously deliver fluid for conditions such as lymphedema and lipomas, as determined by the treating physician. It is not

intended to be used as an IV infusion pump

Variant Information

Device Information

In vitro diagnostic devices

04 Electro mechanical medical devices

Specific Conditions

No Specific Conditions included on Record