

Department of Health and Aged Care

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Precise Medical Supplies Pty Ltd

for approval to supply

Precise Medical Supplies Pty Ltd - Pump, roller

ARTG Identifier 399056

ARTG Start Date 9/11/2022

Medical Device Included Class IIa **Product Category**

GMDN 36664

GMDN Term Pump, roller

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

Manufacturer Details	Address	Certificate number(s)
HK Surgical Incorporated	1271 Puerta Del Sol San Clemente , California , 92673 United States Of America	DV-2022-MC-19918-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Pump, roller

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100. Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 399056 ARTG Start Date: 9/11/2022