



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 409973 Ophthalmopro Pty Ltd - Ophthalmic anaesthesia needle

ARTG entry for Medical Device Included Class IIa

Sponsor Ophthalmopro Pty Ltd

Postal Address PO Box 42, Kew, VIC, 3101
Australia

ARTG Start Date 2/06/2023

Product Category Medical Device Class IIa

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
PSI/EYE-KO INC dba Anodyne Surgical	804 Corporate Centre Drive O'Fallon, Missouri USA, 63368 United States Of America

Products

1 . Ophthalmic anaesthesia needle

Product Type	Single Device Product	Effective Date	2/06/2023
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GMDN 47610 Ophthalmic anaesthesia needle

Intended Purpose Used to administer anesthesia for eye surgery in various spots around the eye cavity.

Specific Conditions

No Specific Conditions included on Record

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