



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 428910 Freyr Australia Pty Ltd - Minimally Invasive Micro Sclerostomy (MIMS) Device - Micro-sclerostomy system control unit

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** Freyr Australia Pty Ltd  
**Postal Address** 46 Dora Street, Blacktown, NSW, 2148  
Australia  
**ARTG Start Date** 28/11/2023  
**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
Sanoculis Ltd	10 Landau Street , Kiryat-Ono, 5555110 Israel

### Products

#### 1 . Minimally Invasive Micro Sclerostomy (MIMS) Device - Micro-sclerostomy system control unit

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	28/11/2023
<b>GMDN</b>	65716 Micro-sclerostomy system control unit		
<b>Intended Purpose</b>	The Minimally Invasive Micro Sclerostomy (MIMS) Device is intended for the reduction of elevated Intraocular Pressure (IOP). The MIMS Activation Device is a multi-use component used to activate the surgical tool in order to remove the sclero-corneal tissue. It is intended for use in an operation room, by trained professional ophthalmologists and personnel.		

### Specific Conditions

No Specific Conditions included on Record

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Public Summary