



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

**Public Summary**

|                                |                                                                                                |
|--------------------------------|------------------------------------------------------------------------------------------------|
| <b>Summary for ARTG Entry:</b> | 459806 Freyr Australia Pty Ltd - Diode Laser Therapy Systems - Hair-removal diode laser system |
| <b>ARTG entry for</b>          | Medical Device Included Class IIb                                                              |
| <b>Sponsor</b>                 | Freyr Australia Pty Ltd                                                                        |
| <b>Postal Address</b>          | 46 Dora Street, Blacktown, NSW, 2148<br>Australia                                              |
| <b>ARTG Start Date</b>         | 16/08/2024                                                                                     |
| <b>Product Category</b>        | Medical Device Class IIb                                                                       |
| <b>Status</b>                  | Active                                                                                         |
| <b>Approval Area</b>           | Medical Devices                                                                                |
| <b>Conditions</b>              |                                                                                                |

- 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.

|                               |                                                                                |
|-------------------------------|--------------------------------------------------------------------------------|
| <b>Manufacturers</b>          |                                                                                |
| <b>Name</b>                   | <b>Address</b>                                                                 |
| BEIJING UNT Technology Co Ltd | M2-1 Area Xinggu Development Zone<br>Pinggu District, Beijing, 101200<br>China |

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|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Products</b>                                                          |                                                                                                                                                                                                                                                                                                                                                      |
| <b>1 . Diode Laser Therapy Systems - Hair-removal diode laser system</b> |                                                                                                                                                                                                                                                                                                                                                      |
| <b>Product Type</b>                                                      | Single Device Product                                                                                                                                                                                                                                                                                                                                |
| <b>Effective Date</b>                                                    | 16/08/2024                                                                                                                                                                                                                                                                                                                                           |
| <b>GMDN</b>                                                              | 58786 Hair-removal diode laser system                                                                                                                                                                                                                                                                                                                |
| <b>Intended Purpose</b>                                                  | The Diode laser therapy system is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. |
| <b>Specific Conditions</b>                                               |                                                                                                                                                                                                                                                                                                                                                      |
| No Specific Conditions included on Record                                |                                                                                                                                                                                                                                                                                                                                                      |

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