



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

## Public Summary

<b>Summary for ARTG Entry:</b>	362068	Freyr Australia Pty Ltd - Abortion suction system manual aspirator
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	Freyr Australia Pty Ltd	
<b>Postal Address</b>	46 Dora Street, Blacktown, NSW, 2148 Australia	
<b>ARTG Start Date</b>	15/04/2021	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	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
WomanCare Global	1640 Roanoke Boulevard Salem, Virginia, 24153 United States Of America

### Products

#### 1 . Abortion suction system manual aspirator

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	15/04/2021
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**GMDN** 62162 Abortion suction system manual aspirator

**Intended Purpose** All aspirators and cannulae are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients. Clinical indications for uterine aspiration with product are: treatment for incomplete abortion for uterine sizes up to 12 weeks from last menstrual period (LMP), first trimester abortion (menstrual regulation), and endometrial biopsy. Applications for endometrial biopsy may include: cases of infertility, abnormal uterine bleeding, amenorrhea, and screening for endometrial cancer or screening for endometrial infections.

### Specific Conditions

No Specific Conditions included on Record

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