



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 362068 Freyr Australia Pty Ltd - Abortion suction system manual aspirator

ARTG entry for Medical Device Included Class 1

Sponsor Freyr Australia Pty Ltd

Postal Address 46 Dora Street, Blacktown, NSW, 2148
Australia

ARTG Start Date 15/04/2021

Product Category Medical Device Class 1

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
WomanCare Global	1640 Roanoke Boulevard Salem, Virginia, 24153 United States Of America

Products

1 . Abortion suction system manual aspirator

Product Type	Single Device Product	Effective Date	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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