



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 356865 Freyr Australia Pty Ltd - Cannula, uterine, suction

ARTG entry for Medical Device Included Class Is

Sponsor Freyr Australia Pty Ltd

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

ARTG Start Date 16/03/2021

Product Category Medical Device Class Is

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 . Cannula, uterine, suction

Product Type	Effective Date
Single Device Product	16/03/2021

GMDN 32655 Cannula, uterine, suction

Intended Purpose All Ipas aspirators and compatible cannulae are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients. Clinical indications for uterine aspiration include treatment of 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: abnormal uterine bleeding, amenorrhea, and screening for endometrial cancer or endometrial infections.

Specific Conditions

No Specific Conditions included on Record

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