



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 321668 Ebos Group Australia Pty Ltd - Foetal Doppler system

ARTG entry for Medical Device Included Class IIa
Sponsor Ebos Group Australia Pty Ltd
Postal Address PO Box 100, KINGSGROVE, NSW, 1480
Australia
ARTG Start Date 12/08/2019
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

Bistos Co Ltd

Address

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Galmachi-ro Jungwon-gu Seongnam-si
, Gyeonggi-do,
Korea - Republic of

Products

1. Foetal Doppler system

Product Type	Single Device Product	Effective date	12/08/2019
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GMDN 34040 Foetal Doppler system

Intended purpose A hand-held, battery-powered device consisting of a measuring and display unit and probe designed to detect foetal heart beats using ultrasound/Doppler technology with monochrome display.

Specific Conditions

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