Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

ACRA Regulatory Services Pty Ltd

for approval to supply

ACRA Regulatory Services Pty Ltd - HeraBEAT ultrasound fetal heart rate monitor pack - Foetal Doppler system

ARTG Identifier	311986
ARTG Start date	28/11/2018
Product Category	Medical Device Included Class IIa
GMDN	34040
GMDN Term	Foetal Doppler system
Intended Purpose	HeraBEAT ultrasound fetal heart rate monitor pack consists of handheld fetal doppler device, HeraBEAT smartphone software application, and ultrasound transmission gel; intended to be used by pregnant women in the home environment for detection fetal heart rate

Manufacturer Details	Address	Certificate number(s)
HeraMED Ltd	6 Meir Ariel Street POB 8576 , Netanya, 4059300 Israel	DV-2018-MC-20355-1

ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. HeraBEAT ultrasound fetal heart rate monitor pack - Foetal Doppler system

Product Specific Conditions

No specific conditions have been recorded against this entry.