

Singapore Medical Device Register (SMDR)

Device Information

Product Number	DE0019287
Registration Date	31-May-2017
Change Notification Approval Date	11-Sep-2025
Product Name	Circle Cardiovascular Imaging cvi42
Intended Use	cvi42 is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images and cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.
Device Risk Classification	Class B
Medical Specialty	Radiology / Imaging
Are any models supplied sterile?	No

Product Owner

Product Owner Name	Circle Cardiovascular Imaging Inc.
Product Owner Address	CANADA Western Canadian Place- North Tower, Suite 1800, 707, 8th Avenue SW, T2P 1H5, Calgary, Alberta

Registrant

Company Name	PE PHARMA PTE. LTD.
Company Address	1, COMMONWEALTH LANE 07 - 12, ONE COMMONWEALTH, 149544 Singapore

Device Models

No.	Model Name	Identifier	UDI-DI	DM-DI	Place of Manufacture
1	CircleCardiovascular Imaging cvi42	cvi42			Canada