

**Health Sciences Authority**  
11 Biopolis Way #11-01 Helios  
Singapore 138667  
Tel: 65 6866 3400 Fax: 65 6478 9076  
Website: www.hsa.gov.sg



31/05/2017

Peng Ying Kun

PHARMENG TECHNOLOGY PTE. LTD.  
1 FUSIONPOLIS PLACE, GALAXIS, #03-20, SINGAPORE  
138522

Dear Sir/Mdm,

Please refer to your Pre-Market Application submitted on 18/04/2017.  
Job Reference No.: MD17634993V  
Device Name(s): <Please refer to attached Schedule>

The Health Sciences Authority has completed the review of this application, and we are pleased to inform you that the information provided has been adequate to demonstrate the quality, safety, and performance of the product for supply. The application is approved effective from the date of this letter and approved indication(s) can be found in the schedule attached.

The registration of this medical device shall not be construed as approval of the use(s) of this medical device. Use of this medical device may be subject to restrictions under the Private Hospitals and Medical Clinics Act, Medical Registration Act or any other applicable legislation (e.g. Radiation Protection Act).

Please contact Ng Wei Beng, Regulatory Specialist, at Tel: or E-mail: [NG\\_Wei\\_Beng@hsa.gov.sg](mailto:NG_Wei_Beng@hsa.gov.sg) should you need further clarification.

Yours sincerely,  
Wong Woei Jiuang (Ms)

A handwritten signature in black ink, appearing to read 'Wong Woei Jiuang', with a horizontal line underneath.

Director, Medical Devices Branch  
for Group Director  
Health Products Regulation Group

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## THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	CIRCLE CARDIOVASCULAR IMAGING CVI42	Intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format Version 5.6

END OF PRODUCT LIST