ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GB7605919-32314**
Registration No.:

Tarikh Sah Pendaftaran: **05/08/2024 - 04/08/2029**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **BIOD MEDICA SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:
B-06-38A, BLOCK B, SUNWAY GEO, JALAN LAGOON SELATAN, BANDAR SUNWAY, 47500 SUBANG JAYA SELANGOR DARUL EHSAN

Peranan establismen
Role of establishment
Wakil Diberi Kuasa
Authorized Representative

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: *Registration No.:*	**GB7605919-32314**	Tarikh Sah Pendaftaran: *Registration Validity Date:*	**05/08/2024 - 04/08/2029**

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**CARDIOVASCULAR MAGNETIC RESONANCE (MR) AND COMPUTED TOMOGRAPHY (CT) IMAGING SOFTWARE APPLICATION**		
Kelas *Class*	**CLASS B**	Jenama *Brand*	**CVI42**
Kelompok *Group*	**SINGLE**	Produk Identifikasi *Product Identifier*	**CVC1X590**
Nama dan alamat pembuat: *Name and address of manufacturer*	**CIRCLE CARDIOVASCULAR IMAGING INC. 1100, 800 – 5 AVE SW CALGARY, AB, T2P 3T6 CANADA**		

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
ARAS 6, PRIMA 9, PRIMA AVENUE II, BLOCK 3547
PERSIARAN APEC, 63000 CYBERJAYA.
TEL : (+603)8230 0300

Ref : MDR-20250515-116097
Date : 19-06-2025

To whom it may concern,

Dear Sir/Madam,

CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE (CATEGORY 2)

The above matter is referred.

Please be informed that your change notification request for the medical device as follows has been approved.

Establishment Name	: **BIOD MEDICA SDN. BHD.**
Medical Device Registration Certificate No.	: GB7605919-32314
Medical Device Name	: CARDIOVASCULAR MAGNETIC RESONANCE (MR) AND COMPUTED TOMOGRAPHY (CT) IMAGING SOFTWARE APPLICATION
Description of Change	: **Refer Attachment of Approval**

2. This change notification shall be attached together with the medical device registration certificate. The validity of this document shall follow the date as stated in the medical device registration certificate.

Thank you,

MURALITHARAN PARAMASUA
CHIEF EXECUTIVE
Medical Device Authority,
Ministry of Health Malaysia.

Ref : MDR-20250515-116097
Date : 19-06-2025

Attachment of Approval

Change Notification for Category 2

TYPE OF CHANGE(S)	DESCRIPTION OF CHANGE(S)
5.5.1 Change in manufacturing facility, process and quality management system (QMS)	
(a) All changes to manufacturing and/or sterilisation facilities with no changes to the manufacturing and/or sterilisation processes.	CIRCLE CARDIOVASCULAR IMAGING INC. WESTERN CANADIAN PLACE - NORTH TOWER SUITE 1800, 707 8TH AVENUE SW CALGARY ALBERTA T2P 1H5