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: **GC8288223-137875**   Tarikh Sah Laku Pendaftaran: **28/06/2023 - 27/06/2028**
Registration No.:   *Registration Validity Date:*

Sijil ini adalah dengan ini diberi kepada: **GLOBAL HEALTHCARE SG SDN.BHD**
This certificate is hereby issued to:

yang beralamat di: **LOT 43824, JALAN TECH VALLEY 2/1, BANDAR
                                                                          SRI SENDAYAN, DARUL KHUSUS, MALAYSIA,**
which is located at: **71950 SEREMBAN
                                                                          NEGERI SEMBILAN DARUL KHUSUS**

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

No. Pendaftaran: **GC8288223-137875**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **AITRIAGE™ V1**
Medical Device Name

Kelas *Class*	**CLASS C**	Jenama *Brand*	**V1**

Kelompok **SYSTEM**
Group

Nama dan alamat
pembuat:
Name and address of
manufacturer

TIIM HEALTHCARE PTE. LTD.
203 HENDERSON ROAD #12-13, HENDERSON INDUSTRIAL PARK,
159546
SINGAPORE

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	aiTriage	v1	Software version: v1.0.0. aiTriage is a software-assisted chest pain triage and reporting Software as a Medical Device, providing a non-invasive risk stratification score of a chest pain patient's risk of 30-day Major Adverse Cardiac Events (MACE).
2	Patient Monitor	PMD-250	PMD250 patient monitor can monitor physiological signals including HR (Heart Rate), NIBP (non-invasive blood pressure), SpO2, PR (pulse rate), TEMP (body temperature) and RESP (Respiration rate).
3	SPO2 Sensor	BST09001S	SPO2 measurement is a continuous, non-invasive method of measuring Hemoglobin oxygen saturation.
4	Temperature Probe	TJW0041B2	Patient Monitor uses thermistor temperature sensor to measure body temperature

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
5	Blood Pressure Cuff	MH002RC12HP1	Patient Monitor uses the method of oscillographic vibration to measure noninvasive blood pressure, Oscillography inspects the change of blood pressure in artery and the pressure in the cuff
6	Charging Line	BSL61	The battery will be charged automatically when Patient Monitor is connected to USB equipment, no matter Patient Monitor is powered on or not.
"End Of Product List"			