# MEDICAL DEVICE LISTING

## Dated: 18/11/2022

Note: This device information is abstracted from the Singapore Medical Device Register.

### DEVICE INFO

**TIIM aiTriage ™** [TIIM Healthcare Pte Ltd]

**Intended use** - aiTriage™ is intended to capture, analyze and report the MACE score (0-100) and category (low, medium, and high risk) of the patient for chest pain triage. While the aiTriage software is connected to the PMD-250 device, patient vital sign signals are transmitted to the aiTriage software in real-time for continuous recording. After vital sign recording, the signals are analyzed, and a final report is generated based on the HRV information calculated from the entire ECG recording and the patient's HEAR score input. The system is indicated for use on patients 21 years or older, who may be presenting with non-traumatic chest pain, and have normal sinus rhythm.

**Device System Info** - [Device with measuring function]

**Models** -
aiTriage (Model #: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 stratifi cation score of a chest pain patient's risk of 30-day Major Adverse Cardiac Events (MACE).

**Category** - (CLASS C), [Cardiovascular]

**Registration Info** - Device Registration No. : DE0507506 , Listing Date : 18/11/2022 , Expiry Date : 17/11/2023

**Product Owner**

TIIM Healthcare Pte Ltd: 2 LENG KEE ROAD, #04-09, THYE HONG CENTRE, SINGAPORE 159086

**Registrant**

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

**Distributor**

No Distributor(s)

**Manufacturing Site**

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

### CONDITIONS

1. **Post-market Surveillance**
   - PLC001 - Supply of the medical devices is subject to post-market duties as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

## 2. Advertisement

- PLC003 - Any advertisement shall not contain any statement to the effect, whether directly or indirectly, that the use of the above mentioned device is being promoted or endorsed by the Health Sciences Authority.

- PLC004 - The above mentioned device shall not be advertised to the general public.

- PLC005 - The indicated use of the product must be clearly stated in your product advertisement, inclusive of brochures, pamphlet and others, and may not refer to any representation relating to the following scheduled diseases and conditions: Blindness, Cancer, Cataract, Drug addiction, Deafness, Diabetes, Epilepsy or fits, Hypertension, Insanity, Kidney Disease, Leprosy, Menstrual disorders, Paralysis, Tuberculosis, Sexual function, Infertility, Impotency, Frigidity and Conception and pregnancy.

## 3. Change of Registrant or Product Owner

- PLC007 - A change of the Product Owner or Registrant may result in the suspension or cancellation of the Device Listing on the SMDR if the change has not been approved by HSA.

## 4. Professional use only device

- PLC008 - The supply of the abovementioned device is restricted to qualified practitioner.

## 5. Change Notification

- PLC013 - Any technical/ review/ administrative change, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this device listing shall require approval from the Authority prior to supply of these medical devices, unless otherwise specified by the Authority. Failure to notify such changes to medical devices may result in suspension or cancellation of this device listing in accordance to Section 37(1)(b)(ii) of the Health Products Act.

- PLC014 - Any notification change, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this device listing shall be notified to the Authority prior to supply of these medical devices. Failure to notify such changes may result in suspension or cancellation of this device listing in accordance to Section 37(1)(b)(ii) of the Health Products Act.

## 6. Other Regulatory Requirements

- PLC019 - A record of every import and supply including the date, quantity and batch/lot number of the device shall be kept, stating the device name, name and address of the purchaser/supplier, device registration number and the stock balance.

- PLC020 - Cold-chain condition must be maintained for temperature sensitive medical devices.

- PLC023 - The product owner shall assist the Health Sciences Authority with any request for information on medical devices registered under this listing. The product owner shall provide post-market support and assistance to the registrant for medical devices registered under this listing.

- PLC024 - This device listing is valid on the condition that the registrant remains authorised by the product owner in accordance to the letter of authorisation (LOA).

- PLC034 - All medical devices in this listing shall be labelled with Unique Device Identifier (UDI) and the relevant UDI data elements and shall be updated on the

Singapore Medical Device Register (SMDR) by the respective UDI compliance dates as set out on the Authority's website.

**7. Software**

- PLC026 - All records, including a Unique Licence Number or equivalent, for each software download/supply shall be kept and made available to the Authority upon request.

- PLC027 - A software maintenance program shall be available to all users. All information including the records of this maintenance program shall be retained and made available upon request by the authority.

**8. Others**

- The Registrant shall submit summary report of the \r\ncomplaints\/feedback received globally through post-\r\nmarket monitoring on a half-yearly basis for the first \r\nyear and annually thereafter, for up to 3 years from \r\ndate of device registration. The due date for the first \r\nreport to be submitted will be 15 May 2023.

**Close**