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## PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device      Device Category      Registrant      Product Owner      Importer      Wholesaler      Advanced Search

### Device Info

Device Name: **Lev El Diagnostics HeartTrends™ System** [Lev El Diagnostics of Heart Diseases Ltd.]

Description: The HeartTrends™ software is intended for the analysis, summary and reporting of up to three channels of pre-recorded ambulatory ECG data. It is also intended to provide measurements of the MPW (Multiple Parameter Weighted) HRV. The Dy/Dx value can be used as a prognostic score to assist in diagnosis of coronary artery disease for which the physician renders his/her own opinion. HeartTrends™ does not offer a diagnostic opinion to the user.

Medical Specialty Area: Cardiovascular

HS Code: 90181900

HSA Product code: Refer to CRPNS

Medical Device Class: Class B medical device

Device Registration No: DE0017663

Registration Date: 20/11/2015

Change Notification Approval Date: Not Applicable

Expiry Date: 19/11/2016

Device System Info: [System or Procedure Pack], HeartTrends™ is a medical software that analyses R-R intervals measurements captured from a certified off-the-shelf Holter during a heart-test-in-rest short procedure.

### Product Owner

1. [Lev El Diagnostics of Heart Diseases Ltd.](#) [Lev El Diagnostics of Heart Diseases Ltd.] Kibbutz Shefayim, P. O. Box ...