

EC CERTIFICATE

Number: 3902202CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

(Devices in Class IIa, IIb or III)

Manufacturer:

Lev-El Diagnostics of Heart Diseases Ltd.

45 Haneviim St.

Jerusalem 9514103

Israel

For the product category(ies)

Software based medical devices for diagnostics-aid of ischemic heart diseases using Heart Rate variability analysis

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 3902198CN, initially dated 12 March 2019

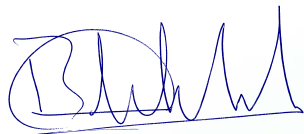
Addendum, initially dated 12 March 2019

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2024
Issued for the first time: 12 March 2019

EU Extension of Validity Regulation 2023/607: 31 December 2028

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 3902202CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Software based medical devices for diagnostics-aid of ischemic heart diseases using Heart Rate variability analysis

Issued to:

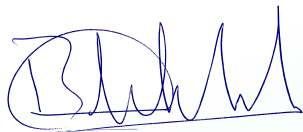
Lev-El Diagnostics of Heart Diseases Ltd.
45 Haneviim St.
Jerusalem 9514103
Israel

This certificate covers the following product(s):

- HeartTrends Client (Class IIa)
- HeartTrends Server (Class IIa)

Initial date: 12 March 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt
Certification Manager

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