

DECLARATION OF CONFORMITY



We,

Norav Medical Ltd.

4 Hamada st., Yokneam, Israel 2069202

hereby declare under our sole responsibility that the medical device(s) as detailed below, for the application of *PC based Resting ECG, Stress Test ECG, Telemetry ECG, and Ambulatory ECG* conform and meet the full provisions of the Medical Device Directive 93/42 EEC, as amended by the Directive 2007/47/EC and the implementation of the Medical Device Directive into British Legislation, SI 618:2012.

We have appointed the Certification Body

BSI - British Standard Institution

Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

to assess and register our Quality Management System according to *EN ISO 13485:2016* and to act as our *Notified Body* to audit us in accordance with *Annex II* of the Medical Devices Directive.

Notified Body ID:	<u>2797</u>		
ISO Certificate ID:	<u>MD 680735</u>	Issue date:	<u>24.01.2018</u> Expiry date: <u>26.02.2025</u>
EC Certificate ID:	<u>CE 680339</u>	Issue date:	<u>22.08.2018</u> Expiry date: <u>16.08.2023</u>
MDSAP Certificate ID:	<u>MDSAP 693097</u>	Issue date:	<u>12.06.2020</u> Expiry date: <u>26.02.2025</u>

The medical device(s) listed below have been classified in accordance with the Medical Devices Directive classification rules of: **Annex IX, Rule 10** - "Active devices intended for diagnosis, if they are intended to allow direct diagnosis or monitoring of vital physiological processes (Electrocardiographs)"

Classification: **Ila**

List of applied Standards: **NV-01.00.06**

Products covered by this declaration:

1200M	PC based system for 12 lead Resting ECG
1200T	Simple single channel ECG Add-on device with Trigger output
1200HR	PC based High Resolution system for 12 lead Resting- and Stress Test ECG
ECG-USB1(EX, EXR)	Simple single channel ECG Add-on device
1200S	PC based system for 12 lead Resting- and Stress Test ECG
1200W + WR	Wireless PC based system for 12 lead Resting- and Stress Test ECG
Telemetry System	PC based Telemetry system; NM-700 with NR-314-T
NR Series	NR-302, NR-314, NR-314-T, NR-1207, NR-1207-3, NR-1207-E

Available Software Options for the *PC-ECG 1200 Series*:

S1 & S2 (Stress Test ECG & Advanced Stress Test ECG), **I1** (Measurement tool for Resting ECG), **I2 & I3** (Measurement tool, incl. Automatic Interpretation, **M1** (12 lead long term Resting ECG), **L1** (Late Potential Analysis), and **H1** (Heart Rate Variability Analysis)

Analysis Software for Ambulatory ECG (Holter): **NH-301**

Patient and ECG Management System (database):

NEMS-A & NEMS-Q	PC based data management tool for Local & Network applications
NEMS-Cloud	WEB based data management tool

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed **Norav Medical GmbH, Christof-Ruthof-Weg 10, 55252 Mainz-Kastel, Germany**, to act as our Authorized Representative in the European Community.

This declaration of conformity is valid from its issuance until the expiry date of the accompanying CE Certificate.

Authorised Signatory:

Michal Yeger

Name

30.05.2022,

Date

Yokneam, Israel

Place

QA & RA Director

Position

Signature

Michal Yeger
QA & RA Director
Norav Medical Ltd.
4 Hamada st. Yokneam
2069202, Israel

