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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

Digitally signed by Prodan Sveatoslav
Date: 2023.07.27 17:37:55 EEST
Reason: MoldSign Signature
Location: Moldova

No. **CE 680339**

Issued To:

Norav Medical Ltd.
4 Hamada Street
Yokneam Illit
2069202
Israel

In respect of:

Design and manufacture of PC based ECG systems and ambulatory ECG systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

INTREPRINDEREA MIXTA S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA MUN. CHISINAU

First Issued: **2018-08-22** Date: **2021-05-20** Expiry Date: **2023-08-16**

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Supplementary Information to CE 680339

Issued To:

Norav Medical Ltd.
4 Hamada Street
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Israel

NBOG Code	Device Names	Intended purpose
Class IIa		
MD 1302	Norav PC-ECG 1200 Series Hardware ECG Devices (1200S, 1200M, 1200HR, 1200T, 1200W, 1200WR) and ECG-USB1.	N/A for class IIa
MD 1302	Norav NR Series Hardware ECG devices (NR-314-T, NR-302, NR-314, NR-1207, NR-1207-3, NR-1207-E).	N/A for class IIa
MD 1111	Software options for 1200 Series: Resting-ECG, Mobile ECG, (S1 & S2) Stress Test ECG, (I1) ECG-Measurement, (I3) Automatic Interpret, (M1) ECG long term Monitoring, (L1) Late Potential Analysis, (H1) Heart Rate Variability Analysis, NEMS-A (local database), NEMS-Q (network database).	N/A for class IIa

First Issued: **2018-08-22** Date: **2021-05-20** Expiry Date: **2023-08-16**

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4 Hamada Street
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2069202
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NBOG Code	Device Names	Intended purpose
Class IIa		
MD 1111	Analysis Software to analyze Ambulatory ECG Recordings made with Holter Recorders (NH-301).	N/A for class IIa
MD 1111	Telemetry software (NM-700).	N/A for class IIa

First Issued: **2018-08-22** Date: **2021-05-20** Expiry Date: **2023-08-16**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 680339**
Date:	**2021-05-20**
Issued To:	**Norav Medical Ltd.** **4 Hamada Street** **Yokneam Illit** **2069202** **Israel**

Subcontractor:	**Service(s) supplied**
Norav Medical GmbH Christof-Ruthof-Weg 10 55252 Mainz-Kastel Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System
Certificate History

Certificate No: **CE 680339**
Date: **2021-05-20**
Issued To: **Norav Medical Ltd.**
4 Hamada Street
Yokneam Illit
2069202
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Date	Reference Number	Action
22 August 2018	8795337 9641677	First Issue. Transfer from another notified body. Certificate Renewal.
19 February 2019	8798565	Traceable to NB 0086.
Current	9788581	Device table change. Device name replaced by device description. Intended purpose corrected for class IIa devices. Withdraw devices: Blue-ECG, ECGLAN [Green], ECGLAN [V-Green], (I2) Automatic Interpret, NEMS Cloud, ECGBT2, 1200M-G. Added Devices: NR-302, NR-314, NR-1207, NR-1207-3 & NR-1207-E. Change in scope. Former scope "Design and manufacture of Advanced PC based ECG systems and ambulatory ECG systems.", updated scope "Design and manufacture of PC based ECG systems and ambulatory ECG systems." Change in EU representative address from "Norav Medical GmbH, Otto-von-Guericke-Rinf-10, 65205 Wiesbaden, Germany" to "Norav Medical GmbH, Christof-Ruthof-Weg 10, 55252 Mainz-Kastel , Germany" Correction of NBOG Codes for class IIa devices. Former code MD 1301, current code MD 1302.

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