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NORAV Medical GmbH
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European Declaration of Conformity to the Regulation (EU) 2017/745 (MDR) of the European Parliament, and of the Council of 5th April 2017 on Medical Devices

CE 2797

This Declaration of Conformity has been issued under the sole responsibility of the

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SRN: **DE-MF-000006715**

based on certification of a full *Quality Assurance System* and in accordance with *Article 19* and *Annex IV, Chapter I and III* of the *Regulation (EU) 2017/745 (MDR)*.

We hereby declare that all the Medical Devices mentioned in this declaration comply with the applicable requirements of the Regulation *(EU) 2017/745 (MDR)* and all other Union legislation.

Risk Classification:	*Class IIa*	*Valid for all the Medical Devices mentioned in this declaration.*
Classification Rule: According to Annex VIII, Chapter III of the Regulation (EU) 2017/745 (MDR)	*Rule 10*	"Active devices intended for diagnosis and monitoring are classified as Class IIa – if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters…"
Conformity Assessment Route:	*Annex IX*	Assessment based on a Quality Management System and on the Assessment of Technical Documentation.
Notified Body:	*BSI (2797)*	**British Standard Institution** ***BSI Group – The Netherlands B.V.*** *Say Building, John M. Keynesplein 9* *1066 EP Amsterdam* *– The Netherlands –* *Tel.: +31 20 346 0780* *WEB: www.bsigroup.com*

Certificates issued by BSI:	Type	Number	Issue Date	Validity
	ISO 13485:2016	*MD 663099*	*07.05.2024*	*06.05.2027*
	CE 2797	*MDR 789298*	*03.04.2025*	*02.04.2030*

Products covered by this declaration:

Trade name:	*Norav PC-ECG 1200 Series*
Product Type:	*Digital ECG System for Cardio-Vascular Diagnostics in Resting-ECG and Cardiac Stress Test*
Basic UDI-DI:	*426049856DE55252NMDECT9*
Intended Purpose:	*The intended purpose of the PC-ECG 1200 Series Devices is for Patients who require:* ***Resting ECG*** *– to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in adults and paediatric populations.* ***Cardiac Stress Test*** *– to monitor the contractile capability of the heart muscle via ECG while the Patients do exercises at various levels at bicycle, treadmill, or other means.*

Model	Specification, if applicable	EMDN Code	UDI-DI No.
PC-ECG 1200M	Digital Resting-ECG only	Z12050302	04260498564125
PC-ECG 1200S	Digital Resting-ECG & Stress Test	Z12050101	04260498564149
PC-ECG 1200T	Digital Resting-ECG with Trigger-Out	Z12050302	04260498561902
PC-ECG 1200HR	High Resolution ECG recording	Z12050101	04260498564217
PC-ECG 1200HRT	High Resolution ECG recording with Trigger Out	Z12050101	04260498566815
PC-ECG 1200W	Wireless Resting- ECG & Cardiac Stress Test	Z12050101	04260498565016
PC-ECG 1200WR	Receiver for Wireless ECG	Z12050101	04260498561971
ECG-USB1 (EX/EXR)	1-Channel Resting-ECG with Trigger-Out	Z12050302	04260498567584
GEH-ECG 1200	Wireless Resting- ECG & Cardiac Stress Test	Z12050101	04260498567003
Quark C12x	High Resolution ECG recording with Trigger Out	Z12050101	04260498567423
Quark T12x	Wireless Resting- ECG & Cardiac Stress Test	Z12050101	04260498567485

Trade name:	*Norav PC-ECG 1200 Series – Software Options*
Product Type:	*Additional optional features for PC-ECG 1200 Software for specific applications.*
Basic UDI-DI:	*426049856DE55252NMKEYVQ*
Intended Purpose:	*The intended purpose of the Norav Software is to add more diagnostic features to the Digital PC-ECG 1200 Series products or to allow the analysis of specific ECG recordings, such as Ambulatory ECG (Holter) or Telemetry-ECG, or to provide Patient Database application.*

Model	Specification, if applicable	EMDN Code	UDI-DI No.
PC-ECG Option S1	Cardiac Stress Test, incl. interface to Ergobikes/Treadmills	Z12050192	04260498563012
PC-ECG Option S2	Advanced Cardiac Stress Test, incl. interface to E/T	Z12050192	04260498563029
PC-ECG Option I1	Resting-ECG Measurement	Z12050192	04260498562824
PC-ECG Option I3	Resting-ECG Measurement with Interpretation	Z12050192	04260498562855
PC-ECG Option M1	Long term Resting-ECG Monitoring	Z12050192	04260498562879
PC-ECG Option L1	Late Potential Analysis	Z12050192	04260498562862
PC-ECG Option H1	Heart Rate Variability Analysis	Z12050192	04260498562817
SW-NH-301	Ambulatory ECG Analysis	Z12050401	04260498562978
SW-NM-700	Telemetry ECG, incl. monitoring of up to 7 Patients	Z12050802	04260498562992
SW-NEMS-A	ECG Recording Database for single user	Z12059009	04260498562664
SW-NEMS-Q	ECG Recording Database for network environment	Z12059009	04260498562671
SW-NEMS-Web	ECG Recording Database for web space (cloud based)	Z12059009	04260498568192

Trade name:	*Norav NR Series*
Product Type:	*Digital ECG Recording Device for Cardio-Vascular Diagnostics*
Basic UDI-DI:	*426049856DE55252NMNRSX2*
Intended Purpose:	*The intended purpose of the NR Series ECG Recording Devices is for Patients who require:* ***Resting ECG*** *– to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in adults and paediatric populations.* ***Cardiac Stress Test*** *– to monitor the contractile capability of the heart muscle via ECG while the Patients do exercises at various levels at bicycle, treadmill, or other means.*

Model	Specification, if applicable	EMDN Code	UDI-DI No.
NR-1207-E	Wireless Resting- ECG & Cardiac Stress Test	Z12050101	04260498565498
NR-1207-3	Wireless Resting- ECG & Cardiac Stress Test & Holter	Z12050101	04260498565436
*** Requires Holter Analysis Software (see PC-ECG 1200 in Software Options above)**			

Trade name:	*Norav NR Series*
Product Type:	*Digital ECG Recording Device for Ambulatory ECG (Holter)*
Basic UDI-DI:	*426049856DE55252NMAMBTG*
Intended Purpose:	*The intended purpose of the NR Series Recording Devices for Ambulatory ECG (Holter) is to discover "rare" conditions (for example Syncope) or patterns of arrhythmia, rate abnormalities, or to monitor and check the correct function of an implanted pacemaker.*

Model	Specification, if applicable	EMDN Code	UDI-DI No.
NR-302	3ch/48h Ambulatory-ECG (Holter Monitoring)	Z12050403	04260498565115
NR-314	3ch/14days Ambulatory-ECG (Holter Monitoring)	Z12050403	04260498565214
NR-314-P	3ch/14days Ambulatory-ECG (Holter Monitoring)	Z12050403	04260498568208
NRP-USB	USB Docking Station for the NR-314-P	Z12050403	04260498568253
NR-1207	12ch/7days Ambulatory-ECG (Holter Monitoring)	Z12050403	04260498563814
*** Requires Holter Analysis Software (see NH-301 in Software Options above)**			

Trade name:	*Norav NR*
Product Type:	*Digital ECG Recording Devices and Transmitter for Telemetry-ECG*
Basic UDI-DI:	*426049856DE55252NMTELWB*
Intended Purpose:	*The intended purpose of the NR Series Recording Device NR314-T is especially for Patients in Rehabilitation Measure (e.g., after infarction or heart surgery) to monitor the contractile capability of the heart muscle via ECG while the Patients do exercises at various levels.*

Model	Specification, if applicable	EMDN Code	UDI-DI No.
NR-314-T	Telemetry-ECG Transmitter, 3 channel	Z12050803	04260498565306
*** Requires Telemetry-ECG Software (see NM-700 in Software Options above)**			

This EU Declaration of Conformity is signed for and on behalf of NORAV Medical GmbH by:

Name: *Willi Schlosser* Function: *QA Manager & PRRC* Signature:

Place: *Mainz-Kastel* Date: *03.04.2025* Stamp:

NORAV Medical GmbH
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