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DECLARATION OF CONFORMITY

Norav Medical GmbH declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the requirements of Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Manufacturer Name	***Norav Medical GmbH***
Manufacturer Address	*Christof-Ruthof-Weg 10* *55252 Mainz-Kastel* *– Germany –*
UK Responsible Person	*Not applicable at the date of this declaration.* *(Where required for market placement, a UK Responsible Person will be formally appointed and identified on product labelling and MHRA registration.)*
Product Name	*Norav NR Series* *Norav PC-ECG 1200 Series* *Associated Software PC-ECG 1200, NH-301, and NM-700*
Product Model Number	*Norav NR Series Products (302, 314, 314-P, 314-T, 1207, 1207-E, 1207-3)* *Norav PC-ECG 1200 Series Products (1200M, S, T3, HR, HRT, W2, WR, ECG-USB1 [EX and EXR], GEH-ECG 1200, Quark C12x, Quark T12x)*
Classification	*Class IIa, Rule 10 (UK Regulations, Part II, Section 7, referring to Annex IX of Directive 93/42/EEC)*
Conformity Assessment Route	*Audit of the full quality assurance system (Part II of the UK MDR 2002, Annex II (as modified by Part II of Schedule 2A to the UK MDR 2002))*
UK Approved Body Name and ID #	*Name:* ***BSI*** *Identification Number:* ***0086***
UKCA Certificate Number	*Number:* ***UKCA 789338*** *Issue Date:* ***16.04.2025***
Name	*Willi Schlosser*
Title	*QA Manager and PRRC*
Signature	
Date	*09.01.2026*