We, the

Norav Medical GmbH
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hereby declare under our sole responsibility that the Norav Medical products ***PC-ECG 1200 Series*** and ***NR-Series*** are designed and manufactured in accordance with the following standards:

Standard	Description	Applicable for:	
		PC-ECG 1200	*NR Series*
(EU) 2017/745 (MDR)	Regulation of the European Parliament and of the Council of 5 April 2017 on Medical Devices, amended by *Regulation **(EU) 2023/607***.	✓	✓
SOR/98-282	Medical Devices Regulations of the Canadian *Food and Drugs Act*; Health Canada	✓	✓
TG(MD)R 2002	The Australian *Therapeutic Goods (Medical Devices) Regulations 2002*, made under the *Therapeutic Goods Act 1989*	✓	✓
MHLW MO 169	The Japanese *Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices* (MHLW Ministerial Ordinance No. 169 in 2004)	✓	✓
UK MDR 2002	United Kingdom Medical Device Regulation	✓	✓
AMDD:2015	*ASEAN Medical Devices Directive* – Jakarta: ASEAN Secretariat, September 2015 (Member States of the Association: *Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand and Viet*)	✓	✓
EN ISO 13485:2016 + A11:2021	International Standard for Medical Devices, amended by ***A11:2021*** – Quality Management Systems – Requirements for regulatory purposes	✓	✓
EN ISO 14971:2019-12	Medical devices – *Application of Risk Management to Medical Devices*	✓	✓
ISO TR 24971:2020	Medical Devices — Guidance on the Application of ISO 14971	✓	✓
ISO 14155:2020	Clinical investigation of medical devices for human subjects —Good clinical practice	✓	✓
Regulation (EU) 2021/2226	Application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	✓	✓
ISO 15223-1:2021	The International Standard specifies Symbols to be used to express information supplied for Medical Devices (M.D. Labelling)	✓	✓
ISO 20417:2021	Medical Devices – Information to be supplied by the Manufacturer	✓	✓
2011/65/EU	Directive of the European Council on the restriction of the use of certain hazardous substances in Electrical and Electronic Equipment (RoHS II)	✓	✓
2014/30/EU	Directive of the European Council on the Electromagnetic Compatibility (EMC)	✓	✓
2014/53/EU	Directive of the European Council on the Radio Equipment (RED)	✓	✓
EN 62304:2006/A1:2015	Defines the life cycle requirements for Medical Device Software – amendment ***A1:2015*** is intended to add requirements to deal with legacy software.	✓	✓
EN 62366-1:2015/A1:2020	Specifies a Process for a Manufacturer to analyse, specify, develop and evaluate the Usability of a Medical Device – Part 1: Application of usability engineering to medical devices	✓	✓
IEC 60601-1:2005/A:2020	General requirements for Basic Safety and Essential Performance	✓	✓
IEC 60601-1-2:2014/A2020	General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility - Requirements and tests	✓	✓
IEC 60601-1-6:2010 +A1:2013 +A2:2020	General requirements for Basic Safety and Essential Performance – Collateral standard: *Usability*	✓	✓

Standard	Description	Applicable for:	
		PC-ECG 1200	*NR Series*
IEC 60601-1-11:2020	General requirements for Basic Safety and Essential Performance – Collateral standard: *Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment*.	✓	✓
IEC 60601-2-25:2011	International Standard for Medical Electrical Equipment: Particular requirements for the Basic Safety and Essential Performance of Electrocardiographs	✓	✓
IEC 60601-2-47:2015	International Standard for Medical Electrical Equipment: Particular requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic systems	---	✓
EN ISO 10993-1:2018	Biological Evaluation of Medical Devices — Part 1: *Evaluation and Testing within a Risk Management Process*	✓	✓
EN ISO 10993-5:2009	Biological Evaluation of Medical Devices — Part 5: *Tests for In-Vitro Cytotoxicity*	✓	✓
EN ISO 10993-10:2021	Biological Evaluation of Medical Devices — Part 10: *Tests for Irritation and Skin Sensitization*	✓	✓
MDCG 2018 – 1 Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	✓	✓
MDCG 2020 – 1	Guidance on Clinical Evaluation (MDR) of Medical Device Software	✓	✓
MDCG 2020 – 3 Rev. 1	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to Devices covered by certificates according to MDD	✓	✓
MDCG 2020 – 5	Guidance on Clinical Evaluation - Equivalence	✓	✓
MDCG 2021 – 19	Guidance notes on integration of the UDI within an Organization's Quality Management System	✓	✓
MDCG 2023 – 3 Rev. 1	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745	✓	✓
MDCG 2024 – 1	Guidance on the Vigilance System for CE marked Devices	✓	✓
MDCG 2024 – 16	Manufacturer Information on Interruption or Discontinuation of Supply of certain Medical Devices acc. to Article 10a of Regulation (EU) 2024/1860 amending Regulation (EU) 2017/745	✓	✓
Regulations 44ZC, 44ZD, 44ZE, 44ZF, 44ZG, 44ZL, 44ZM and 44ZQ	Amendment to the UK Medical Devices Regulations (MDR) 2002: Medical Devices Post-market Surveillance Requirements (Amendment) (Great Britain) Regulations 2024	✓	✓

This List of Applied Standards is authorized for and on behalf of NORAV Medical GmbH by:

Willi Schlosser	*QA Manager & PRRC*
Name	*Position*
17.09.2025 *Mainz-Kastel*	
Date *Place*	*Signature*