

Date: 27.11.2025

**To Whom It May Concern**

**DECLARATION OF CONFORMITY REACH & RoHS**

We, the

**Norav Medical GmbH**  
Christof-Ruthof-Weg 10  
55252 Mainz-Kastel  
– GERMANY –

a manufacturer of medical products duly incorporated under the laws of Germany, hereby declares in particular with regard to the following products:

**PC-ECG 1200 Series**, *Models 1200M, 1200S, 1200T3, 1200TUSB, 1200HR, 1200HRT, 1200W2, ECG-USB1 (EX / EXR);*  
**NR Series**, *Models NR-1207-E and NR-1207-3 for Resting-ECG and Cardiac Stress Test;*  
**NR Series**, *Models NR-302, NR-314, and NR-1207 for Ambulatory ECG Monitoring (Holter Monitoring);*  
**OEM Products**, *NBP-One and NBP-24 NG for Ambulatory Blood Pressure Monitoring (ABPM)*

which we manufacture and supply to our distribution partners worldwide, that they fully comply with the requirements of the Regulation **(EC) No 1907/2006** of the European Parliament and of the Council, concerning the *Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)*.

1. According to the structure of the REACH Regulation, Norav Medical GmbH is a manufacturer of "ITEMS" for its EU customers. Norav Medical GmbH does not produce nor use "substances" or "preparations", and the products mentioned above do not involve the intentional release of any substances. No registration, pre-registration or authorization is required for the products mentioned above.
2. Regarding the requirements of **Article 33** of the REACH Regulation "Duty to communicate information on substances in articles", we declare that none of the **SVHCs** (*Candidate list of Substances of Very High Concern for Authorization*, published in accordance with **Article 59** of the REACH Regulation) are present in any of our articles in a concentration of 0.1% or higher.
3. Regarding the requirements of **Article 67** of the REACH Regulation "A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction", we declare that none of the substances subject to use restriction are present in any of our articles.


As the REACH Regulation is frequently updated, Norav Medical will make further adjustments and update this declaration accordingly in the event of significant changes, such as the inclusion of *Substances of Very High Concern* in **Annex XIV** or the inclusion of substances with restrictions in **Annex XVII**.

If no new declaration is submitted, the validity of the information contained in this declaration remains unaffected.

**Declaration of Conformity RoHS**

We also hereby confirm that our products mentioned above comply with all requirements and provisions regarding the stability exemptions from the European Directive **2011/65/EU** (RoHS 2) and the European Delegated Directive **2015/863/EU** (RoHS 3).

For and on behalf of Norav Medical GmbH

  
Willi Schlosser  
QA Manager and PRRC

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