

## Izjava o sukladnosti

u skladu s Uredbom (EU) 2017/745 o medicinskim proizvodima, Prilog IV, iz svibnja 2017.

**BEE Medic GmbH**  
SRN DE-MF-000034511  
Sattlertorstr. 48a  
91301 Forchheim  
Njemačka

izjavljuje pod vlastitom isključivom odgovornošću da su proizvodi

### **NeuroAmp II i NeuroAmp II 5.s**

Br. artikla A01000 i Br. artikla A01001

Osnovni UDI: 426241876NeuroAmpRLS

NeuroAmp II koristi se za digitalizaciju biosignala s elektroda ili perifernih senzora te za prijenos podataka u stvarnom vremenu na osobno računalo (PC). Mora se koristiti u kombinaciji s odgovarajućim softverom i računalima.

|                      | <b>NeuroAmp II</b> | <b>NeuroAmp II 5.s</b> |
|----------------------|--------------------|------------------------|
| <b>Serijski br.:</b> | 10000 - 10999      | 11000 - 50000          |

na koje se ova izjava odnosi, sukladni su sa sljedećom uredbom:

Postupak ocjenjivanja prema Uredbi (EU) 2017/745 o medicinskim proizvodima, Prilog IV, IX i povezanim propisima

Klasifikacija prema Uredbi (EU) 2017/745 o medicinskim proizvodima, Prilog VIII  
Aktivni medicinski proizvod klase I prema pravilu klasifikacije 13

Ovaj proizvod ispunjava CS (zajedničke specifikacije) i označen je CE oznakom zbog ispunjenja općih zahtjeva sigurnosti i učinkovitosti prema Uredbi (EU) 2017/745 o medicinskim proizvodima.

BEE Medic GmbH  
Dr. Bernhard Wandernoth  
*[vlastoručni potpis]*  
Direktor

Forchheim, 04.02.2025.

# Declaration of Conformity

according to Regulation (EU) 2017/745 on medical devices, annex IV dated May 2017

**BEE Medic GmbH**  
**SRN DE-MF-000034511**

*Sattlertorstr. 48a  
91301 Forchheim  
Germany*

*declares under its sole responsibility that the products*

***NeuroAmp II and NeuroAmp II 5.s***  
***Article No. A01000 and Article No. A01001***  
***Basic UDI: 426241876NeuroAmpRLS***

The NeuroAmp II is used to digitize biosignals from electrodes or peripheral sensors and transmit the data in real-time to a PC computer. It must be used in combination with appropriate software and computers.

|            |               |                |
|------------|---------------|----------------|
|            | NeuroAmp II   | NeuroAmp II5.s |
| Serial No: | 10000 - 10999 | 11000 - 50000  |

to which this declaration relates is in conformity with the following regulation:

*Evaluation procedure according to Regulation (EU) 2017/745 on medical devices, annex IV, IX and related laws*

Classification according to Regulation (EU) 2017/745 on medical devices, annex VIII  
*Active medical device class I according to classification rule 13*

This product *fulfils the CS (Common Specifications)* and has been CE-labelled due to the fulfilment of the general safety and performance requirements according to *Regulation (EU) 2017/745 on medical devices*.



BEE Medic GmbH  
Dr. Bernhard Wandernoth  
Managing Director

Forchheim, 04.02.2025

A handwritten signature in blue ink, appearing to be 'B. Wandernoth', is written over the printed name and date.