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 product

Combination Sensor
Article No. A01003
Basic UDI: 426241876COMBISENSOR2P

A biofeedback sensor to measure galvanic skin response, skin temperature and heart rate to show changes of these parameters for biofeedback applications.

Serial No: 1000 - 1200

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, X, XI 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, annex.*

CE

BEE Medic GmbH

Dr. Bernhard Wandernoth
Managing Director

Forchheim, 31.03.2023