

Izjava o sukladnosti
prema Uredbi (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 svojom isključivom odgovornošću da proizvod

Brummi
Broj artikla: A01005
Osnovni UDI: 426241876BRUMMIEW6H

Brummi je uređaj za taktilnu povratnu informaciju koji služi kao dodatni kanal povratne informacije za primjene biofeedbacka.

Serijski brojevi: 6100-8000

na koji se ova izjava odnosi u skladu je sa sljedećom uredbom:
Postupak ocjene sukladnosti prema Uredbi (EU) 2017/745 o medicinskim proizvodima, prilozi IV, IX, X, XI i povezani propisi.
Klasifikacija prema Uredbi (EU) 2017/745, Prilog VIII:
Aktivni medicinski proizvod klase I prema pravilu klasifikacije 13.

Ovaj proizvod ispunjava ZS (Zajedničke specifikacije) te je označen CE oznakom zbog ispunjavanja općih sigurnosnih zahtjeva i zahtjeva za učinkovitost prema Uredbi (EU) 2017/745 o medicinskim proizvodima.

BEE Medic GmbH
Dr. Bernhard Wandernoth
Direktor
Forchheim, 12.01.2024

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

Brummi
Article No. A01005
Basic UDI: 426241876BRUMMIEW6H

The Brummi is a tactile feedback device that serves as an additional feedback channel for biofeedback applications.

Serial No: 6100 - 8000

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.*



BEE Medic GmbH

Dr. Bernhard Wandernoth
Managing Director

A blue ink signature of Dr. Bernhard Wandernoth, written in a cursive style.

Forchheim, 12.01.2024