# 1 EU Declaration of Conformity

in accordance with regulation (EU) 2017/745 of the Council

We,

**Kamedi GmbH**

Haid-und-Neu-Straße 7
76131 Karlsruhe
Germany
SRN: DE-MF-000006270

declare on our own and sole responsibility that the **accessory for a medical device**

| Product | **heat it® *App*** |
|---|---|
| Product Number<br>Basic UDI-DI | 466<br>4262370294669H |
| Medical Device Class | IIa (MDR - Annex VIII - Implementing Rule 3.3) |
| Intended Purpose | Control and monitor medical device heat it® *Dongle* |

is designed and manufactured in accordance with Regulation (EU) 2017/745, satisfies the general safety and performance requirements (Annex I) and applicable harmonized standards have been applied. The technical documentation shall be kept at the above address.

| | Notified Body |
|---|---|
| NB | **TÜV Süd Product Service GmbH**<br>Ridlerstraße 65<br>80339 München<br>Identification Number: 0123 |
| Conformity Assessment: | (EU)2017/745 Annex IX Chapt. I and III, incl. TD assessment acc. to Para. 4 for at least one rep. device for each category of device |
| Certificates: No. | EU Quality Management System Certificate (MDR)<br>G10 103413 0004 Rev. 00 |

This declaration is only valid for the product with the product number stated above. This declaration is valid beginning with App LOT/Version 2.5.0 and is valid until 2028-07-29. It expires upon issuance of a revised declaration of conformity after modification of the product.

Karlsruhe, 2024-07-29
Stefan Hotz, CCO & PRRC, Kamedi GmbH