System Statement for

heat it®

in accordance with regulation Article 22 - Systems and procedure packs - of Council Regulation (EU) 2017/745.

We,

Kamedi GmbH

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

declare on our own and sole responsibility that the mutual compatibility of the medical device and its accessory mentioned below has been verified. The products are placed onto the market via joint and separate distribution and can be used in combination with each other. All relevant information is provided to the user.

The combination of these devices was subject to appropriate methods of internal monitoring, verification and validation.

Product	**heat it® *Dongle***	**heat it® *App***
Product Number	419	466
Basic UDI-DI	42623702941998	4262370294669H
Class	Medical device IIa	Accessory for a medical device IIa (MDR - Annex VIII - Implementing Rule 3.3)
Intended Purpose	Locally heat an affected skin region to temperatures of about 51 °C for a few seconds (“hyperthermia”)	Control and monitor medical device heat it® *Dongle*
Variants	All heat it® *classic USB-C Dongle* heat it® *classic Lighting Dongle* heat it® *pro USB-C Dongle* heat it® *pro Lightning Dongle*	All heat it® *App for Android* heat it® *App for iPhone*

All devices as named above comply with Regulation (EU) 2017/745, satisfy the general safety and performance requirements (Annex I) and applicable harmonized standards have been applied.

The system is placed onto the market under the following names and variants

heat it® *classic USB-C*	heat it® *classic Lightning*
mosquito® by heat it® USB-C	*mosquito® by* heat it® Lightning
EntertainME Insektenstichheiler by heat it® USB-C	*EntertainME Insektenstichheiler* by heat it® Lightning
heat it® *pro USB-C*	heat it® *pro Lightning*

This declaration is only valid for the product combination with the product numbers stated above. There are no restrictions for combinations for different versions of the devices. This declaration is valid until 2029-02-28 and expires upon issuance of a revised declaration of conformity after modification of the product.

Karlsruhe, 2025-02-28
Stefan Hotz, CCO & PRRC, Kamedi GmbH

1 Appendix

» 'IR_00649_System_Statement_heatit_for_Android_1_1_0_signed.pdf'