

# EU Declaration of Conformity

We,

**Kamedi GmbH**  
Haid-und-Neu-Straße 7  
76131 Karlsruhe, Germany  
SRN: DE-MF-000006270

Kamedi GmbH, declare on our own and sole responsibility that the medical device

Product	<b>heat it® Dongle</b>
Product Number	419
Basic UDI-DI	42623702941998
Medical Device Class	Ila
Intended Purpose	Locally heat an affected skin region to temperatures of about 51 °C for a few seconds ("hyperthermia")

is designed and manufactured in accordance with the following regulations:

## Regulation (EU) 2017/745 on medical devices

The device 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	<b>TÜV Süd Product Service GmbH</b> Ridlerstraße 65, 80339 München, Germany 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) G10 103413 0004 Rev. 00

## **Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)**

The device is designed and manufactured in compliance with directive 2011/65/EU amended by Commission Delegated Directive (EU) 2015/863 and does not contain substances which are restricted by these Directives. Harmonized standards have been applied.

This declaration is only valid for the product with the product number stated above and includes the following variants

*heat it® classic USB-C Dongle*

*heat it® classic Lightning Dongle*

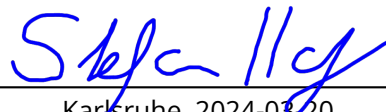
*mosquito® by heat it® USB-C Dongle*

*mosquito® by heat it® Lightning Dongle*

*heat it® pro USB-C Dongle*

*heat it® pro Lightning Dongle*

This declaration is valid until 2028-03-14 and expires upon issuance of a revised declaration of conformity after modification of the product.



Karlsruhe, 2024-03-20  
Stefan Hotz, CCO & PRRC, Kamedi GmbH