

# EU Declaration of Conformity

We,

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

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

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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")

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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.

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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

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## **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.

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

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*heat it® classic USB-C Dongle*

*heat it® classic Lightning Dongle*

*mosquito® by heat it® USB-C Dongle*

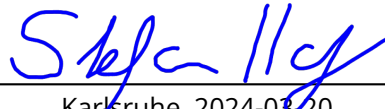
*mosquito® by heat it® Lightning Dongle*

*heat it® pro USB-C Dongle*

*heat it® pro Lightning Dongle*

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



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

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## 1 EU Declaration of Conformity

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

We,

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**Kamedi GmbH**

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

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

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Product	<b>heat it® App for Android</b>
Product Number	99001AN
Basic UDI-DI	42623702999001ANEH
Medical Device Class	Ila (MDR - Annex VIII - Implementing Rule 3.3)
Intended Purpose	Control and monitor medical device <i>heat it® Dongle for Android</i>

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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.

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	Notified Body
NB	<b>TÜV Süd Product Service GmbH</b> Ridlerstraße 65 80339 München 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

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This declaration is only valid for the product with the product number stated above. This declaration is valid beginning with App LOT/Version 2.4.0 and is valid until 2025-07-10. It expires upon issuance of a revised declaration of conformity after modification of the product.

  
  
Karlsruhe, 2023-08-01  
Stefan Hotz, CCO & PRRC, Kamedi GmbH

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# 1 EU Declaration of Conformity

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

We,

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**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**

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Product	<b>heat it® App for iPhone</b>
Product Number	99001IN
Basic UDI-DI	42623702900001IN6T
Medical Device Class	IIa (MDR - Annex VIII - Implementing Rule 3.3)
Intended Purpose	Control and monitor medical device <i>heat it® Dongle for iPhone</i>

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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.

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	Notified Body
NB	<b>TÜV Süd Product Service GmbH</b> Ridlerstraße 65 80339 München 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

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This declaration is only valid for the product with the product number stated above. This declaration is valid beginning with App LOT/Version 2.4.0 and is valid until 2025-07-10. It expires upon issuance of a revised declaration of conformity after modification of the product.

  
Karlsruhe, 2023-08-01   
Stefan Hotz, CCO & PRRC, Kamedi GmbH

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## System Statement for *heat it<sup>®</sup> for Android*

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

We,

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**Kamedi GmbH**

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

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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	<i>heat it<sup>®</sup> Dongle</i>	<i>heat it<sup>®</sup> App for Android</i>
Product Number	419	99001AN
Basic UDI-DI	42623702941998	42623702999001ANEH
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 <i>heat it<sup>®</sup> Dongle</i>
Variant	<i>heat it<sup>®</sup> classic USB-C Dongle</i> <i>mosquito<sup>®</sup> by heat it<sup>®</sup> USB-C Dongle</i> <i>heat it<sup>®</sup> pro USB-C Dongle</i>	All

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 as following variants

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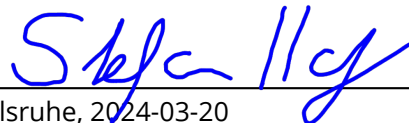
*heat it® classic for Android*

*mosquito® by heat it® for Android*

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*heat it® pro for Android*

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 2028-04-24 and expires upon issuance of a revised declaration of conformity after modification of the product.

A handwritten signature in blue ink that reads "Stefan Hotz".

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

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## System Statement for *heat it<sup>®</sup> for iPhones with USB-C*

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

We,

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**Kamedi GmbH**

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

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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	<i>heat it<sup>®</sup> Dongle</i>	<i>heat it<sup>®</sup> App for iOS</i>
Product Number	419	990011N
Basic UDI-DI	42623702941998	426237029990011NF9
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 <i>heat it<sup>®</sup> Dongle</i>
Variant	<i>heat it<sup>®</sup> classic USB-C Dongle</i> <i>mosquito<sup>®</sup> by heat it<sup>®</sup> USB-C Dongle</i> <i>heat it<sup>®</sup> pro USB-C Dongle</i>	All

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 as following variants

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*heat it® classic for iPhone USB-C*

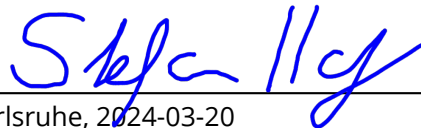
*mosquito® by heat it® for iPhone USB-C*

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*heat it® pro for iPhone USB-C*

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This declaration is only valid for the product combination with the product number stated above. There are no restrictions for combinations for different versions of the devices. This declaration is valid until 2028-04-24 and expires upon issuance of a revised declaration of conformity after modification of the product.

A handwritten signature in blue ink, appearing to read "Stefan Hotz".

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

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## System Statement for ***heat it<sup>®</sup> for iPhones with Lightning***

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

We,

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**Kamedi GmbH**

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

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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	<b><i>heat it<sup>®</sup> Dongle</i></b>	<b><i>heat it<sup>®</sup> App for iOS</i></b>
Product Number	419	990011N
Basic UDI-DI	42623702941998	426237029990011NF9
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 <i>heat it<sup>®</sup> Dongle</i>
Variant	<i>heat it<sup>®</sup> classic Lightning Dongle</i> <i>mosquito<sup>®</sup> by heat it<sup>®</sup> Lightning Dongle</i> <i>heat it<sup>®</sup> pro Lightning Dongle</i>	All

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.

**System Statement heatit for iPhone with Lightning**

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The system is placed onto the market as following variants

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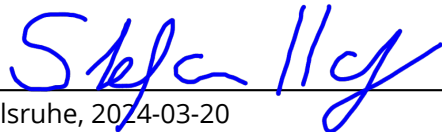
*heat it® classic for iPhone Lightning*

*mosquito® by heat it® for iPhone Lightning*

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*heat it® pro for iPhone Lightning*

This declaration is only valid for the product combination with the product number stated above. There are no restrictions for combinations for different versions of the devices. This declaration is valid until 2028-04-24 and expires upon issuance of a revised declaration of conformity after modification of the product.

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