EU DECLARATION OF CONFORMITY

Document No.: KAPX-DoC-001
Revision: 01
Date of issue: 01/09/2026

1. Manufacturer
Manufacturer: KAPSYS
Registered address: 694 Avenue Maurice Donat – 06250 – Mougins - France
SRN: FR-MF-000058070

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

2. Device identification
Product name: KapX
Product type: Assistive wearable device for visually impaired and blind persons
Model / Product ref: KapX / KAP51000
Basic UDI-DI: 376017745KAPX01BQ
UDI-DI: 03760177451407

3. Intended purpose
KapX is an active medical device intended to provide visually impaired and blind persons with information and assistance regarding their surrounding environment, including obstacle avoidance and environmental information, in order to support their outdoor mobility and autonomy in daily activities.

4. Classification
According to Regulation (EU) 2017/745, Annex VIII:

- Medical Device Classification: Class I
- Classification rule: Rule 13 – All other active devices

The classification has been determined in accordance with Annex VIII of Regulation (EU) 2017/745.

5. Declaration of conformity
We hereby declare that the medical device identified above complies with the applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), as amended.

The device has been designed and manufactured in accordance with the applicable General Safety and Performance Requirements (GSPR) set out in Annex I of Regulation (EU) 2017/745.

The applicable conformity assessment procedure has been performed in accordance with Article 52(7) of Regulation (EU) 2017/745, applicable to Class I medical devices, subject to the conditions applicable to the device.

6. Common Specifications
Common Specifications (CS): Not applicable

No Common Specifications established by the European Commission under Regulation (EU) 2017/745 are applicable to KapX.

Where applicable, conformity with the relevant Common Specifications has been demonstrated as documented in the Technical Documentation.

7. Applicable standards and technical specifications
The conformity of the device has been assessed with reference to the applicable harmonised standards and/or technical specifications, including, where applicable:

- EN ISO 14971 – Medical devices – Application of risk management to medical devices
- IEC 62366-1 – Application of usability engineering to medical devices
- ISO 15223-1 – Symbols to be used with information supplied by the manufacturer
- EN IEC 62368-1:2020+A11:2020 – Audio/video, information and communication technology equipment – Safety requirements

- EN 55032:2015+A1:2020 – Electromagnetic compatibility of multimedia equipment – Emission requirements
- EN 55035:2017+A11:2020 – Electromagnetic compatibility of multimedia equipment – Immunity requirements
- EN 61000-3-2:2019+A2:2024 – Electromagnetic compatibility – Limits for harmonic current emissions
- EN 61000-3-3:2013+A2:2021+A0:2022-01 – Electromagnetic compatibility – Limitation of voltage changes, voltage fluctuations and flicker
- EN 301 489-1 V2.2.3 (2019-11) – Electromagnetic compatibility (EMC) standard for radio equipment and services – Common technical requirements
- EN 301 489-3 V2.3.2 (2023-01) – EMC standard for radio equipment and services – Specific conditions for Short-Range Devices
- EN 301 489-17 V3.3.1 (2024-09) – EMC standard for radio equipment and services – Specific conditions for broadband data transmission systems
- EN 300 328 V2.2.2 (2019-07) – Wideband transmission systems – Data transmission equipment operating in the 2.4 GHz band
- EN 301 893 V2.2.1 (2024-11) – 5 GHz RLAN
- EN 300 440 V2.2.1 (2018-07) – Short Range Devices operating in the 1 GHz to 40 GHz frequency range
- EN 50663:2017 – Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields
- EN 62479:2010 – Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields

Additional standards and technical specifications applicable to the device are identified in the Technical Documentation and the GSPR Compliance Matrix.

8. Other applicable Union legislation
Where applicable, the device also complies with the relevant applicable Union legislation, including:

- Directive 2014/53/EU – Radio Equipment Directive (RED)
- Directive 2011/65/EU – Restriction of the Use of Certain Hazardous Substances (RoHS), as amended by Commission Delegated Directive (EU) 2015/863
- Directive 2012/19/EU – Waste Electrical and Electronic Equipment (WEEE)

The applicable conformity assessment and technical documentation for these requirements are maintained by the manufacturer.

9. Notified Body
Notified Body: Not applicable

Conformity assessment procedure: Manufacturer's self-declaration in accordance with Article 52(7) of Regulation (EU) 2017/745. No notified body has been involved in the conformity assessment of the device, subject to the device remaining within the conditions applicable to Class I devices under Article 52(7).

10. Declaration
We hereby declare under our sole responsibility that the device identified above complies with the applicable requirements of Regulation (EU) 2017/745 and other applicable Union legislation identified in this declaration.

This EU Declaration of Conformity is maintained and continuously updated by the manufacturer whenever necessary.

11. Signature
Place of issue: Mougins, France
Date of issue: 01/09/2026

For and on behalf of Kapsys
Name: A. HEKIMIAN
Function: Chairman and Chief Executive Officer (CEO)

Signature:

Date: 01/09/2026