





PRESENTER FULL NAME: Büşra ÜNLÜ

ORGANIZATION: Kardinero Medical Systems Inc.

WORKSHOP NAME: Workshop #1-Digital and Smart Health

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# **Description of the Organisation**





Kardinero is a company that develops and manufactures medical devices, including. diagnostic and therapeutic software applications, and Al solutions. (SME)

Over 30 years of experience in developing and manufacturing PC-based ECG and ECG Stress Test systems hardware and software, and their clinical applications.

Experience in EU project (1 ongoing project)

Roles: Project Partner



# Your Teams' Expertise



- Medical electronic equipment design and R&D
- ECG signal analysis programs
- Cybersecurity



- Medical device quality management and certification
- Big data availability



#### **Your Research Fields**

# **Medical Device Design & Development**

- Embedded systems design
- Hardware and software integration for medical devices
- Multi-parameter medical monitoring systems



# **Cybersecurity in Medical Devices**

- Flexibility in implementing cybersecurity testing and scenarios for medical devices
- Secure data transmission, encryption, and protection of patient information



# **Regulatory Compliance & Certification**

- International medical device regulations, including CE-MDR and FDA requirements.
- Medical device quality management
  - MDR and ISO 13485 certifications



#### Data

- ECG signal analysis
- Multi Signal Analysis
- Big data with availability in ECG Stress Test systems and ECG records
- Clinical applications with clinics for clinical trials and health services research



**Your On-going Projects** 



Ensuring Secure & Safe Connected Medical Devices Design with Zero Trust Principles



# **Project Idea**

**Call Topic:** HORIZON-HLTH-2025-01-CARE-01: End user-driven application of Generative Artificial Intelligence models in healthcare (GenAI4EU)

**Deadline Dates:** 18 Sep 2025

# **□** Objectives:

- Multi-modal physiological data recording
- Al-driven risk estimation, Al-assisted decision support
- Advancement of collaboration and data sharing

### **☐** Expected Results:

- Enhanced Patient Monitoring and Personalized Health Insights
- Clinician Support with AI Recommendations
- High Performance Through Clinical Trials
- Cost Savings and Health System Efficiency



# **Consortium - profile of known partners (if any)**

No	Partner Name	Type	Country	Role in the Project
01				
02			\	
03				
04				
05				



# **Consortium – required partners**

No	Expertise	Type	Country	Role in the project
01				Healthcare Telemedicine Services
02				Healthcare Providers
03				
04				



PRESENTER CONTACT: Büşra Ünlü DETAILS: Biomedical Engineer COUNTRY: Turkey

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