

# Regulated Medical Device / IVD Software Services

## Regulated Medical Device Software for Diagnostics & Monitoring Applications

### SOLUTIONS

#### WHAT WE DO

Ideo Medical Device Software  
and SaMD Solutions

We specialize in developing **cutting-edge software** that enhances the functionality of medical devices and offers **stand-alone software-as-a-device (SaMD)** solutions. Our goal is to empower healthcare professionals to support clinical decision making they need to deliver superior patient care through accuracy, efficiency and real-time data.

#### Software in a Medical Device

- Embedded in, or accessory to, a medical or in-vitro diagnostics physical device
- Subject to the **MDR/IVDR/FDA regulations** that apply to the device as a whole
- Includes low-level **firmware** that controls the **hardware, software** that supports the device **functionality, GUI** through which users operate the device etc. Tools to support **technical service, manufacturing QC** etc may also fall in this category



#### Software as a Medical Device

- Intended to be used for medical purposes without being part of a physical medical or in-vitro diagnostics device
- Subject to **MDR/IVDR/FDA regulations** as a standalone medical device
- Spans a broad **range of applications** including Clinical Decision Support Systems, Imaging Diagnostics Software, Mobile Health Apps, Patient Remote Monitoring, Telehealth Apps, etc



# CAPABILITIES

## HOW WE DO IT

Our software solutions **integrate seamlessly** with various medical devices, transforming them into **intelligent systems that provide enhanced functionality and improved patient outcomes**. Our broad range of **software services** include:



## Broad Range of SW services

### Custom Software Development

Whether using Agile, Waterfall, or other methodologies, we ensure **a controlled development approach** tailored to your quality system or leveraging Idneo's quality standards.

### UI/UX Design

Idneo **UX/UI team** works closely together with the Product Owner and Front-end Development team to speed up the design and implementation of the interface.

### Software Maintenance

Focus on your core development projects and free internal resources by entrusting us with the support, maintenance and evolution of your existing applications.

### Test & Verification Services

Knowledge on the application domain is key for an optimal refinement of the system requirements and their test coverage.

We can perform **final system tests and/or component or module functional tests**, with specialized test teams on HW, FW or SW.

Our development and testing processes follow strictly the medical devices standards **ISO 13485** and **IEC 62304**.

Best test strategy in balancing **manual and automatic testing** to obtain the higher test cost efficiency.

## Software Engineering Expertise



Full Stack Programming

Cloud / Mobile Solutions

Artificial Intelligence

Communications & Cybersecurity

HW/SW Integration

