



Development of a medical app in accordance with the **MDR** (Class IIa)

„As the proud providers of our first certified medical device, we would like to thank infoteam for the very open, constructive and congenial cooperation we have had with them right from the start. Throughout the entire project, we were able to fully rely on infoteam's enormous software expertise.“

*Markus Richter, Head of Development
Hamberger Medical GmbH*

For our customer:

HAMBERGER[®]
MEDICAL



Medical App | iOS | Android | C# | .NET MAUI

MDR | ISO 13485 | IEC 62304 | ISO 14971

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Initial situation

- Hamberger Medical GmbH develops the HARO ECG seat, a toilet seat that is itself a medical device and comes with a medical app to control it, as well as to collect and analyze ECG data
- A consortium is formed for the overall project, covering embedded hardware, embedded software and app development (infoteam Software Group) and other partners
- **Objective 1:** Support for preclinical studies
- **Objective 2:** Standards-compliant development of the medical app in accordance with the MDR (Class IIa) and IEC 62304 (Class B)
- **Objective 3:** Support with the approval process for a medical device (in particular for the medical app as part of the overall approval)

Solution

- Dedicated concept phase for the collection, specification and evaluation of requirements, leading to a detailed estimation of the project scope
- Development of mockups and prototypes for use in preclinical studies
- Development of the medical app for Android and iOS in accordance with the requirements of the MDR, ISO 13485, IEC 62304 and ISO 14971
- Implementation of the requirement: Bluetooth connection with the hardware, PDF export, sharing function (e.g., via e-mail with doctor)
- Software tests (especially with various mobile devices), also in cooperation with the project consortium
- Standards-compliant documentation for approval of the app as a medical device



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