



## CONSULTING FOR SOFTWARE AS A MEDICAL DEVICE (SaMD)

Digital Heroes is a Swiss developer and supplier of modern digital products and strategies as well as online marketing. A range of products from Digital Heroes supports medical professionals on-site using mobile apps. The app functions are in the gray area between a simple health app and SaMD; therefore, the customer is looking for support to develop a better understanding of the regulations in this area. More precisely, Digital Heroes wants to clearly understand the requirements for developing software as a medical product.

### Expert workshop with individual consultation

To evaluate whether the planned functions of the apps met the definition of Software as a Medical Device (SaMD), konplan provided support with regulatory advice about health apps. In a workshop, Digital Heroes was informed about the requirements for placing SaMD on the market. The following topics were covered in the workshop: MDR/IVDR, Intended Use for SaMD classification, EU/USA market launch, medical device development processes, conformity assessment procedures, relevant standards (IEC 62304, ISO 14971, IEC 62366) and documentation requirements. Digital Heroes was also advised regarding MDR Article 7 for assessment of their advertising documents and the analysis of potential business models. The app developed by Digital Heroes was used as an example to better illustrate the process and provide the most productive workshop results.

### Strategic decision making

Based on the workshop content and discussions, Digital Heroes was able to make prompt decisions regarding the product and their corporate strategy in the SaMD area. In addition, MDR Article 7 could be directly applied to adjusting the public communication materials from Digital Heroes. This allowed Digital Heroes to achieve legal certainty and specifically shape the strategic direction of the company and the product range.

### Result

- Build up regulatory requirements know-how for SaMD and health apps
- Strategic decision for future developments

### Methodology & Technologies

- Remote Workshop and Training

### Scope of Services

- EU/USA, IEC 62304, MDR/IVDR, etc.
- Training requirements for market launch SaMD
- Regulatory Support Classification SaMD
- Workshop SaMD
- Strategic Consulting

 2 days

 1 consultant – konplan  
2 employees – customer

 Support & Operations

### Customer

