Medical Device Software Certification: Strategy policy recommendation and implementation guide

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The new Medical Device Regulation (MDR) of the European Union came into full force on the 26th May 2021 and constitutes a significant tightening of regulations for medical devices in general and for software in clinical environments in particular. Some developers of software present in healthcare today will have to consider if their software is a medical device and what the consequences of choosing compliance and pursuing conformity assessment procedures are.

Introduction

Software manufacturers of vital healthcare software, such as clinical information systems (CIS) and vendor neutral archives (VNA) will have to consider the question of medical device certification in the wake of the new MDR in the European Union (EU) and the rapid development of functionality in healthcare that supports healthcare providers in the diagnosis, prevention, monitoring, treatment or alleviation of disease and injuries. New regulations in the EU but also Switzerland and the United Kingdom have come into force that make it more difficult for software developers to enter or stay in the healthcare market. New technologies such as cognitive services and artificial intelligence are boosting the capabilities of software beyond simple data storage and search.

Objectives

The principal objective of this thesis is to offer a policy recommendation and concept to the management of software companies for certifying existing software products as medical devices. This includes answering the following questions:

- Which regulations apply to Medical Device Software (MDSW) in the following regions: EU, United Kingdom, Switzerland, the United States of America (USA), United Arab Emirates (UAE)?
- By which means can it be determined if a new feature/functionality/module will cause the product in question to be classed as a medical device? Which class of medical device will the product belong to and what are the consequences of a certification for that class?
- If the decision is reached that the innovation which causes the software to be classed as a medical device will be implemented, which steps must the company take to certify the software as a medical device?

Methods

The regulatory environments of all target countries were analysed, considering the applicable regulations, standards, specifications, and guidelines. The environmental analysis of an existing software company in the healthcare field included a stakeholder analysis, Porter's Five Forces framework and a SWOT analysis. The availability of emerging technologies was examined using a product analysis of recent innovations in healthcare. The certification process was limited to the analysis of a conformity assessment according to the MDR.

Results

The work in this thesis has shown that tougher regulations in most countries but especially the EU and Switzerland are already influencing the requirements of healthcare providers in tenders and bids for regulated software. Manufacturers who have been exempt from regulation until now, will have to decide to comply to these requirements or alternatively leave the healthcare market all together. A small market presence in healthcare is no longer competitive, as the financial barrier of regulatory compliance is too high to justify small revenues. Thus, the decision of compliance will not be brought about by advances in software functionality, but by the regulatory requirements of healthcare.

Which class of medical device a software belongs to depends on the intended use the manufacturer defines. Qualification as a class I medical device would be a good first step for entering the regulated healthcare market, but it will be very difficult to define the intented use for a class I medical device, as the MDR all but makes such a definition impossible. The implementation guide and the decision tree accompanying the thesis provide a step-by-step guidance for the decision process and the conformity assessment of all classes of medical devices according to the MDR and detailed instructions on how to pursue them.

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