

Challenges of Software Certification in the Medical Technology Industry

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Organisational matters

- About me
- General information about the writing process

Content of the thesis

- Situation and context
- Research questions
- Approach

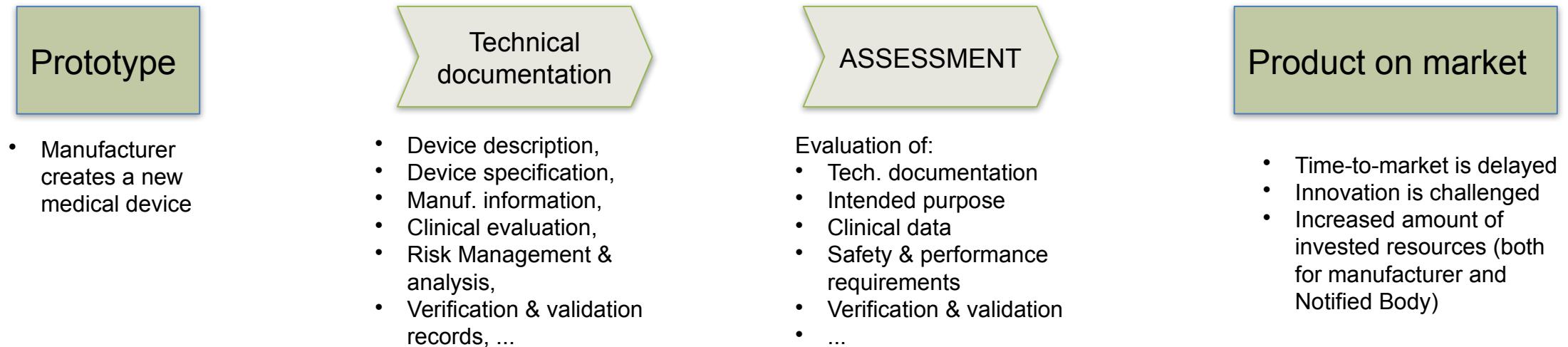
About me: Ilian Boyadjiev

- Student at TUM: Information Systems (Wirtschaftsinformatik) 2018 – 2022
 - MatrNr. 03682704
 - ga87xad@mytum.de / boyadjie@in.tum.de
- Became acquainted with Fortiss GmbH in 2020/2021
 - H. Ruess, Grundlagen der Programm- und Systementwicklung (IN2078)
- Seminar: Service Engineering
- Working student at Catenate GmbH since 2018
 - Backend software development for a business software tool (usage in marketing and sales)
 - Affinity for various project management tasks

General information about the writing process

- Formatting and tools:
 - LaTeX-Template and citation rules: <https://www.in.tum.de/fuer-studierende/pruefungen-und-formalitaeten/abschlussarbeit/>
 - Overleaf
 - Shared file storage by LRZ Sync+Share
- Language: English
- Official start date: 15.02.2022
- Official submission date: 15.07.2022
- Supervisor: Prof. Dr. Florian Matthes
- Advisors: Dian Balta, Yannick Landeck

- Medical devices are a fundamental component of every health care system
- Probability of failure → need for certification
- MDR effective since May 2021 (before that Medical Device Directive was effective)
- New major change to classification: practically there are no devices under Class I anymore
→ most devices are classified one class higher than before
→ need to involve a Notified Body



From a startup perspective, we should research how obligations of the Regulation need to be fulfilled in order to place compliant devices on the market.

- What are the **main challenges** of MDR compliance?
 - Completeness of documentation, consistency of information
 - A method to **continuously verify** the technical documentation
 - Common reasons for rejection, why are there even challenges
- What **processes** are already in place to deal with the challenges?
 - Large scale manufacturing requires an **approach** to **continuously** ensure MDR compliance
 - What kind of processes are involved and what **tools/approaches** are involved
 - Who are the involved **stakeholders, roles**?
 - Transition process from MDD to MDR
- How can a **startup** bring a new product onto the Market?
 - Agile project management approaches are **not** really applicable to compliance projects
 - What processes are needed for small scale manufacturers

Main goal: Market analysis and identification of challenges, processes and strategies to ensure compliance with MDR

Approach

In order to successfully identify and categorize business processes

- A series of **semi-structured interviews** should be conducted
- With **large** manufacturers like Arthrex GmbH, founded in Munich, 1981
- And **small** manufacturers (start ups)
- TUM Venture Labs



A **poster/landmap** is to be created that should contain

- a **summarized overview** of the main research topics and challenges,
- the **results** of the research
- the necessary process steps, measures and documents to successfully and efficiently develop a new compliant medical device from scratch.
- The landmap should serve as a **framework** applicable to startups.

In order to get a better grasp of the topics, the following sources are to be used

- R. Thür, S. Panten, and L. Vogler. "Medical Device Knowledge Units." avasis solutions GmbH,
- Ben-Menahem, S.M., Nistor-Gallo, R., Macia, G. et al. "How the new European regulation on medical devices will affect innovation" (2020)
- T. Lukas, K. Sohrabi, V. Gross, M. Scholtes. "Health Software Product or Software as Medical Device" (2021)
- J. Mantas. "Legal Challenges for IT Service Providers in Pharmacogenomics." (2020)
- R. Ramki. "Regulatory Projects and Agile — Can they go together?" (2019)
- D. Beerbaum. "Applying Agile Methodology to Regulatory Compliance Projects in the Financial Industry: A Case Study Research." (2020)
- Monir El Azzouzi. "Medical Device Easy Podcast"
- and more

Thank you for your attention.