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Doctoral Dissertation
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Digital Therapeutics and AI-based Medical Devices

A Guidance for Safety and Compliance in Europe

By

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Transitioning lab prototypes into medical devices presents a significant challenge due to the stringent requirements of the highly regulated medical device market, which prioritize patient safety. These requirements often necessitate a mature organizational structure and device design, which can be difficult to achieve immediately after the prototype stage.

As digital innovations, particularly in artificial intelligence (AI) and digital therapeutics (DTx), seek to revolutionize healthcare, this work aims to bridge the gap between technological advancements and regulatory demands, ensuring the safe deployment of AI-based medical devices (MAI) and DTx. This research is grounded in the European regulatory framework, a critical reference point, and presents an approach that integrates international standards, with particular emphasis on implications for software as a medical device (SaMD).

The core of this thesis is a risk-based methodology to the design and lifecycle management of SaMD, encompassing planning, development, technical validation, and post-market surveillance. This approach primarily relies on the evaluation and application of the most relevant international standards, incorporating feedback where these standards may lack specificity for new, innovative medical device technologies. Through a series of practical case studies, the work illustrates real-world applications and challenges, emphasizing the importance of both technical and clinical validation to ensure device efficacy and patient safety.

Importantly, the methods and frameworks developed in these case studies have undergone rigorous third-party scrutiny and validation, confirming their compliance with regulatory expectations. The approval by notified bodies marks a crucial milestone, demonstrating not only the viability of the proposed approach for ensuring safety and effectiveness but also its potential as a model for future developments in the digital health technology sector.

By synthesizing theoretical insights with practical case studies, this dissertation contributes to the evolving discourse on digital health, offering a comprehensive guideline for innovators to manage the development of these technologies in alignment with regulatory frameworks. The practical examples provided may serve as a

blueprint for accelerating the adoption of disruptive technologies while establishing a robust foundation for the ongoing development and refinement of standards and guidelines.