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Summary

Medical technology, when effectively regulated, is essential to modern healthcare, safeguarding patient safety and improving health outcomes. Robust regulatory frameworks ensure that medical devices and in vitro diagnostic medical devices (IVDs) meet stringent standards of safety, quality, and performance. In the League of Arab States (LAS), however, significant challenges exist. Fragmented regulatory systems, inconsistencies in oversight, and varying levels of regulatory development across member states underscore the need for a unified and effective approach to medical device governance. These challenges create risks related to device safety, hinder market efficiency, and complicate efforts to address emerging healthcare needs.

This thesis addresses the critical issue of harmonizing medical device and IVD regulations across the LAS to promote safety, efficiency, and innovation. By conducting a comprehensive analysis of the current regulatory landscape, the thesis identifies gaps and disparities while exploring global best practices from leading regulatory models. A particular emphasis is placed on the potential benefits of a unified regional framework, including the establishment of a so-called Arab Medical Device Regulatory Administration (AMDRA) and the implementation of the Arab Conformity (AC) Mark. These proposed mechanisms aim to simplify device registration processes, reduce duplication, and create a single market for these devices that adheres to globally recognized standards.

To enhance regulatory convergence, this thesis also examines the development of the Arab Medical Device Information System (AMDIS). Designed as a centralized regional database, AMDIS would not only address gaps in vigilance but also promote transparency and centralize pre-market approvals information, improve post-market surveillance, and support data-driven decision-making for regulators and manufacturers. By providing comprehensive and accessible information, AMDIS would strengthen collaboration and transparency across the LAS.

Informed by experiences from international organizations and global regulatory frameworks, the thesis underscores the importance of collaboration and capacity building in underdeveloped regulatory environments. While significant obstacles persist, a phased and cooperative approach to harmonization can deliver meaningful benefits for the stakeholders of the healthcare system. Ultimately, this thesis presents a roadmap for achieving a robust and harmonized medical device and IVD regulatory system across the LAS, ensuring patient safety, fostering innovation and contributing to improved healthcare outcomes for the region.