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Hierarchy of Criteria for Evaluating the Product Portfolios of Medical Device Companies*

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Abstract

The implementation of the EU Medical Device Regulation (MDR) has substantially increased regulatory complexity, forcing many companies to reassess and streamline their product portfolios. This study is motivated by the growing need for structured decision-making tools that help medical device firms navigate this evolving regulatory landscape without compromising strategic and financial goals. Despite existing research on MDR's economic impact, the literature lacks practical, criteria-based frameworks tailored to support portfolio optimization under regulatory pressure. To address this gap, we developed a hierarchical multi-criteria model designed specifically for evaluating medical device product portfolios. The model was informed by prior empirical research on MDR's effects across Europe and refined through expert consultations involving professionals from industry and regulation. It incorporates four main criteria—regulatory complexity, market potential, strategic significance, and sales model adaptability—further divided into 21 sub-criteria reflecting both compliance demands and business strategy. The resulting model provides a structured decision-support framework that enables companies to systematically evaluate which products to retain, invest in, or phase out. It facilitates portfolio decisions that account for regulatory burden, profitability, innovation potential, and strategic alignment. The model's practical utility lies in its ability to guide resource allocation, support R&D prioritization, and enhance transparency in decision-making processes. Future work will focus on applying methods such as the Analytic Hierarchy Process (AHP) to assign weights and validate the model through real-world case studies.

Keywords: medical devices; product portfolio; business; management; MCDM

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