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Developing A Model on SME Innovation Strategies—Empirical Evidence and Confirmatory Analysis from Medical Device Industry in Germany

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Abstract

The European Union's regulatory system underwent a significant modification in medical device industry by the implementation of the updated regulation (EU) 2017/745. The research investigated the implications of applying a new MDR to medical SMEs in southern Germany by creating a model utilizing study variables with collected primary data to evaluate the implementation of a new MDR. The research design applied correlational research methodology with simple random sampling techniques. The study finding has been validated statistically by exploratory factor analysis, composite reliability, and confirmatory factor analysis. the research applied inferential data analysis techniques by using SPSS.26 and structural equation modeling (SEM) by using SPSS AMOs. The main study variables are SME's business performance, SME's financial situation, and MDR implementation process. The study statistically highlighted and approved the negative impact of applying the MDR Eu (2017/745) on SME's financial performance, innovation, environmental process, and business.

Keywords: medical devices regulation, innovation theory, inferential statistics, confirmatory factor analysis, transparency, Germany