Fachbereich Angewandte Naturwissenschaften
Studiengang: Regulatory Affairs M.Sc.

Executive Summary

Title: Clinical Evaluation under Regulation (EU) 2017/745: Clinical evaluation strategies for a newly developed class IIb non-implantable medical device – a case study using the example of a hypothetical laparoscopic insufflator

The implementation of Regulation EU 2017/745 (MDR) was driven by the objective of enhancing patient safety through, amongst other provisions, the augmentation of clinical data requirements for medical devices. This thesis undertakes an examination of the impact of this regulation on newly developed, medium-risk (Class IIb) non-implantable active medical devices, with a particular focus on the question of whether a clinical evaluation can be conducted in the absence of a clinical investigation. The study incorporates a systematic literature review, regulatory analysis, expert interviews with notified body reviewers, and a survey of manufacturers, notified body employees and regulatory consultants. The findings demonstrate that MDR significantly raises clinical evidence requirements but lacks clarity on what constitutes "sufficient clinical data" for medium-risk devices. While the regulation permits non-clinical data when clinical data is deemed inappropriate, interpretations of "appropriateness" vary widely.

Interviews with notified body representatives revealed substantial differences in regulatory interpretations. While two of the eight interview partners accepted non-clinical data alone for clinical evaluations in the given scenario, others preferred clinical data from equivalent devices or clinical investigations with varying levels of insistence. The presence of clinical claims was a major factor, with most asserting that such claims necessitate clinical data. The role of data from the same generic device group remains unclear — while widely considered useful for benchmarking, it is not officially classified as clinical data under MDR Article 2(48).

A survey of manufacturers, consultants, and notified body reviewers further supported these findings. But while manufacturers and consultants advocated advanced testing methods such as in silico simulations and test models validated with healthcare professionals, notified body reviewers emphasised standardized bench testing.

Key conclusions underscore the necessity for more explicit MDR guidance on clinical data requirements. The inconsistent application of MDR among notified bodies has the potential to engender uncertainty, resulting in increased regulatory burdens and market delays. Future research should explore non-clinical testing of high-quality and sufficient credibility as an alternative to pre-market clinical data, ensuring a balance between patient safety and medical innovation.

Author: Elisabeth Oltmanns
1st Supervisor: Prof. Dr. Folker Spitzenberger

Date: February 18th, 2025