



UNIVERSITÄT ZU LÜBECK



Master's Program in Biomedical Engineering

Master's Thesis

“Comparison between the new EU Regulation on Medical Devices (MDR) and Council Directive 93/42/EEC (MDD) – New Requirements, Gap Analysis and Impact on GE Healthcare as an example of a European Economic Operator”

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ABSTRACT

After years of technical, scientific, regulatory and public discussion and negotiation, the regulatory framework for medical devices in the European Union is expected to be substantially revised in the second quarter of the year 2017.

The purpose of this thesis is to make a comparison between the new EU Regulation on Medical Devices (MDR) and the currently binding Council Directive 93/42/EEC (MDD), and identify new requirements, gaps and their impact on the company GE Healthcare as a European economic operator.

The thesis explores both - the existing regulatory framework under the MDD and the proposed regulatory framework under the MDR. The most important changes and new requirements of the proposed regulation are identified and presented, along with a high-level overview of the expected impact on the company. The thesis also identifies various new parties (such as importers, distributors and persons responsible for regulatory compliance) and their roles, as well as artefacts (such as new documents, device types, electronic systems, fees and penalties) and corresponding documents affected within the company.

It can be seen that the basic approach for placing a medical device on the EU market by application of conformity assessment procedures will remain the same. Thus, marketing authorization procedures with pre-market approval of devices will not be implemented within the EU. However, strengthened requirements to ensure a higher level of safety for the patients and users of medical devices will be introduced by the MDR.

Among the most relevant requirements for European economic operators are the extension of scope, clearer roles and responsibilities for all economic operators, changed product determination and classification rules, new essential principles, updated requirements for technical documentation and clinical evidence, new requirements for clinical investigations, and new and stricter post-market obligations. These obligations will be legally binding and will require no additional transposition into national laws.

The activities set out in the MDR were categorized into 18 different groups, which represent a simplified overview of the order in which different activities shall be performed for placing a medical device on the market, and the related post-market obligations. For each group, the obligations most relevant as an economic operator are identified, and graphical explanations and summary tables are provided. Each obligation has been evaluated for potential impact on job functions within GE Healthcare (such as RRA, PRA, QA, legal and engineering).

A gap analysis was performed on parts of the MDR within the areas of greatest interest for the company (economic operator obligations; scope, product determination and classification; and conformity assessment option based on QMS). The impacted procedures were identified using appropriate computer tools and mathematical methods for evaluating the gaps, assigning impact values and ranking them as high, medium, low or no impact.

Recommendations are provided for compliance with the requirements of the MDR as well as for incorporating its regulatory requirements into the on-going QMS update within the company.

Further, the most impacted job functions for different groups of activities are summarized. A summary of the most impacted company procedures is also provided, with priorities for revision. A need for drafting five fully new documents was identified.

Following the publication of the MDR, a 3-year transition period will come into effect. This thesis also recognizes the requirements related to the transitional regime and provides an application timeline to implement various obligations.