ABSTRACT

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Title of diploma thesis: Medical devices regulatory framework

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The subject of this diploma thesis is the regulatory framework for the so-called „general" medical devices with a slight overlap in the field of *in-vitro* medical devices. The presented work aims to describe the impact of the planned change in the regulatory framework for medical devices on economic operators in the field of production and distribution of medical devices in the Czech Republic. In this work I gradually deal with the historical development of the regulatory framework for goods in the European Communities and subsequently the European Union and the specific regulation of for medical devices. I deal in detail with the multilevel regulatory framework and the relationships between its components. I focus in more detail on the key change in the regulatory framework, which is represented by the hitherto ineffective EU Medical Devices Regulation 2017/745 and government bills to prepare the Czech legal system for the adoption of this directly effective European Union legislation.

The main parts of the work are chapters 5 and 6 in which, I deal with the potential impacts of the planned change on business activities of the addressees of the regulatory framework. Those chapters focus in more detail on the new institutes of software regulation, new, stricter requirements for clinical evaluation and the biggest problems observed, which is the risk of insufficient capacity of notified bodies and insufficient implementation, which is caused by non-adoption of some important implementing regulations. Furthermore, I focus on the potential risks that changes in the regulatory framework entails and the foreseen benefits that a change in the regulatory framework will bring in the safety and effectiveness of medical devices for general population.

I extensively discuss the benefits of the change of regulatory framework paradigm to overcome one of the biggest weaknesses of the current regulatory framework, where one and the same product may have different regulatory status in different EU Member States, as confirmed in the judgment of the European Court of Justice in case no. No. C-109/12 in the borderline case of products between medicinal products and medical devices, known to under the popular name Lyocentre. Overcoming this principle will be achieved precisely by virtue of the multilevel interconnected regulatory framework for medical devices.

Keywords: Medical devices, regulatory framework, MDR,