## Selected Issues of Medical Device Legislation


## Abstract

This thesis deals with the legal regulation of medical devices in force at the time of its creation, with a focus on general medical devices. The thesis is divided into two main parts. In the first part, the thesis focuses on a comprehensive and detailed analysis of the basic definitions of the field of medical devices, including the definition of the conditions under which computer software used in the healthcare sector is considered a medical device. In particular, the definition of a medical device and an in vitro diagnostic medical device are subject to detailed analysis.

The second part of the thesis deals in detail with the life cycle of a medical device at the time of the entry into force of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and Act No. 375/2022 Coll., on medical devices and in vitro diagnostic medical devices. This section discusses in detail the obligations of medical device manufacturers and their authorised representatives where the manufacturer is established outside the European Union. Within this section, emphasis is placed on the institution of the declaration of conformity, CE marking and the certification process for medical devices. This is followed by an analysis of the obligations of distributors of medical devices and the related legal framework for the activities of importers when medical devices are not placed on the EU market by the manufacturer itself but by a legally separate entity. This chapter examines in detail the institutes of prescription and dispensing of a medical device. The subsequent analysis focuses on the obligations of health service providers within the meaning of Act No. 372/2011 Coll., on health services and conditions of their provision, when they use medical devices in the provision of health care. The last part of the thesis deals in detail with the analysis of the regulation of advertising of medical devices after the amendment brought by Act No. 90/2021 Coll. in connection with the implementation of the MDR. The work thus provides a suborbid descriptive analysis of the obligations of entities involved in the production of a medical device and its commissioning or delivery to a particular patient.



**Key words:** medical devices, MDR, Medical Devices Act