Medical device regulation and its impact on the industry: A case study of Czech companies

Jan Maci[1], Martin Matejicek[2], Lukas Peter[3], Frank Lefley[4], Petra Maresova[5]

1 *University of Hradec Kralove, Faculty of Informatics and Management, Department of Economics, Czech Republic, ORCID: 0000-0002-6315-7991, jan.maci@uhk.cz;*
2 *University of Hradec Kralove, Faculty of Informatics and Management, Department of Economics, Czech Republic, ORCID: 0000-0002-8548-3114, martin.matejicek@uhk.cz;*
3 *University of Hradec Kralove, Faculty of Informatics and Management, Department of Economics, Czech Republic, ORCID: 0000-0003-4351-8291, lukas.peter@uhk.cz;*
4 *University of Hradec Kralove, Faculty of Informatics and Management, Department of Economics, Czech Republic, ORCID: 0000-0001-8367-7102, frank.lefley@uhk.cz;*
5 *University of Hradec Kralove, Faculty of Informatics and Management, Department of Economics, Czech Republic, ORCID: 0000-0002-1218-501X, petra.maresova@uhk.cz.*

Abstract: *The implementation of regulations is often seen as a necessary tool to mitigate market failures and safeguard consumer interests. The Medical Device Regulation (MDR) is a recent regulation specifically designed for the production of medical devices, aiming to ensure their safety and effectiveness. This article focuses on Czech companies and seeks to examine and quantify the effects of the MDR on their operations, considering both economic and procedural impacts. Through the analysis of primary and secondary data, this study endeavors to shed light on the repercussions of the MDR on the companies in question. The findings suggest that the MDR will have a negative impact on the profitability of these companies, consequently influencing their operational strategies. One key factor contributing to this negative outcome is the inability of the companies to transfer the increased costs resulting from regulatory requirements to their customers. As a result, affected companies are forced to make adjustments to their product portfolios, reducing their range of offerings. The research reveals that the perception of the MDR among the companies is predominantly negative. This negative sentiment arises primarily due to the financial burdens imposed by the regulation and the other associated impacts discussed in the article. Furthermore, the MDR is not perceived as a catalyst for innovation within the industry. By quantifying the effects of the MDR on Czech companies, this article provides valuable insights into the real-world implications of this regulatory framework. The findings highlight the challenges faced by companies in adapting to and complying with the MDR, particularly in terms of its impact on profitability and product offerings. This research serves as a reminder of the complex interplay between regulations, economic outcomes, and industry dynamics. Ultimately, it emphasizes the importance of considering the potential ramifications of regulations and their effects on businesses and markets.*

Keywords: *Medical device regulation, regulation, economic impact, innovation, product portfolio.*

JEL Classification: *K23.*

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Introduction

Regulation is used to correct market failure, protect consumers, and improve the business environment. It has both positive (e.g., greater consumer safety) and negative (e.g., increased costs for companies) impacts and can also drive innovation (Blind, 2016).

From a broader perspective, the effects of regulations can be monitored by various indicators (Bayar & Diaconu Maxim, 2020; Broughel & Hahn, 2022; Razavi et al., 2017). According to Maci and Maresova (2022), costs are the most commonly considered variable when evaluating the impact of regulations from an individual microeconomic point of view. Tu (2020) notes that legislative changes can increase costs for businesses in the medical device sector, leading to a negative relationship between regulatory burden and productivity. Specifically, a 1% increase in cost intensity reduces labor productivity by 0.1%. Tu (2020) also found that compliance costs are lower for larger companies with higher revenue. Markiewicz et al. (2017) offer a detailed insight into the thought process of manufacturers when developing a medical device, specifically in the early assessment stage, through results derived from semi-structured interviews. Aware of this problem, governments around the world are coming up with new regulations that should ideally reduce the social as well as medical cost incurred for medical innovation (Konishi et al., 2018) and thereby enhance the chance for the emergence of such innovations that will increase the desirable feeling of satisfied health care needs of the population (Antošová et al., 2022).

The complexity of regulatory changes is evident in the European medical device market, including the Czech Republic. Regulation 2017/745 EU (MDR), effective since May 26, 2021, aims to enhance consumer safety and health protection. However, it poses challenges, particularly for small and medium-sized companies. The new MDR imposes stricter requirements than the previous Medical Device Directive (MDD), such as more precise requirements for clinical safety evaluation. Assessing clinical safety based on similarity to existing products is now more challenging; the manufacturer will now need access to the competing product's technical documentation. Post-market monitoring and clinical data collection are also more defined. Higher requirements usually entail higher costs for innovation, product launch, distribution, sale, and service of medical devices. Such an assumption in the form of increased costs for MDR in the case of software was also expressed by Becker et al. (2019).

In response to the implementation of the European Union's Medical Device Regulation (MDR), several academic authors have already addressed various aspects and broad impacts of this legislation. Wilkinson and Van Boxtel (2020) discuss the new approach to the clinical evaluation of medical devices in the EU, emphasizing the addition of intended clinical benefits to traditional safety and performance considerations. Niemiec (2022) expresses concerns regarding the performance of medical artificial intelligence devices and examines how the MDR, with its stringent safety and quality standards, aims to improve their safety and performance. Bianchini and Mayer (2022) highlight the necessity of understanding the key aspects of MDR, underlining its implications for the entire lifecycle of medical devices and its potential to enhance the efficiency of the innovation process. Carl and Hochmann (2023) present a two-year comparative study assessing the impact of the MDR on the orthopedic aids industry, focusing on challenges faced by companies, such as increased workload, resource expenditure, and downsizing of product portfolios. Collectively, these studies underscore the multifaceted impacts of the MDR on the medical device industry, ranging from clinical evaluation to market innovation, and the overarching necessity for companies to strategically adapt to these regulatory changes.

Just like the above, this article also seeks to provide a perspective on the impacts of MDR. It specifically focuses on the impact on businesses from the point of view of their economy and management. In retrospect, we can observe and evaluate whether this regulation, among other impacts, can be classified as one that has become a catalyst for further growth and development of companies and their innovation or whether the opposite is the case. This is where we see the current gap in practical, but also theoretical, observation-supported knowledge about the effects of regulation on process and financial management, as well as the innovative activity of companies in the sector.

Therefore, this paper aims to evaluate the impact of newly effective regulations on the medical device industry in the Czech Republic. Data from a questionnaire survey

and economic indicators of surveyed companies, along with other common indicators, such as device classification, are analyzed. However, it should be noted that the full impact of the regulation is not yet known due to ongoing adaptation and potential effects of the COVID-19 pandemic.

In keeping with the aim of the paper, the following research questions have been set.

RQ1: Does the company size affect the potential or perceived impacts of MDR?

RQ2: Do economic conditions of the company, such as business performance or financial health, influence the adaptation of activities to comply with MDR, as well as the perception of MDR as such?

RQ3: Are the effects of MDR reflected in the product portfolio of the company?

RQ4: Can satisfaction with the form of MDR be an innovation driver for medical device development?

The study is divided into four thematic areas, each focusing on various aspects of MDR. The first area, explored through *RQ1*, examines how MDR affects companies of diverse sizes. The aim is to determine if MDR harms some companies due to limited resources while others have an easier time with the regulation due to more resources. The second area, covered by *RQ2*, focuses on the economic impact of MDR on businesses. The research area aims to determine how companies adapt to the economic impact of MDR, including shifting increased costs onto customers or adjusting product portfolios, while also examining the impact of these changes on innovation activity. The third area (*RQ3*) overlaps with the second but focuses more on the processes involved in changes to product portfolios and innovation activity. The aim is to identify how businesses adapt to MDR and reveal any adverse effects on product groups. Finally, *RQ4* examines overall satisfaction with MDR in relation to the innovative activity of the company. The aim is to determine if businesses perceive MDR as a new challenge providing new business opportunities.

The purpose of the research presented in this paper is to identify those impacts of MDR that are already apparent in order to draw attention to any possible overregulation and start a discussion on any possible MDR adjustments that might be needed for easy, efficient, but safe practice in the medical device industry.

1. Specifics of the medical device market – European Union and the Czech Republic

The MDR is a European regulation affecting the entire EU market, of which the Czech Republic is a part. For this reason, we present selected characteristics of the medical device market in the EU as a whole and in the Czech Republic, which is the country where the questionnaire survey was conducted. Both these economic areas are characterised below in terms of innovations (patents), employment, companies, expenditures, MedTech market volume, and trade.

1.1 Medical device market in the EU

In 2020, approximately 33,000 medical technology companies were operating in Europe, with Germany having the most significant number, followed by Italy, Great Britain, France, and Switzerland. Small and medium-sized enterprises (SMEs) comprise around 95% of the industry, with the majority employing fewer than 50 people (Medtech Europe, 2021). Healthcare spending in Europe is estimated to be 11% of GDP, with less than 1% of this spent on medical technologies. The European market for medical devices and in vitro diagnostics is estimated to be around EUR 140 billion, with Germany, France, the United Kingdom, Spain, and Italy having the largest markets (Medtech Europe, 2020). Europe has a positive medical device trade balance of EUR 8.7 billion (2020), with the US, China, Mexico, and Japan being Europe's main trading partners for medical devices. The medical technology industry invests heavily in research and development, with an average global R&D investment rate estimated at around 8% (Evaluate, 2018). The industry filed over 14,200 patent applications with the European Patent Office in 2020, with medical technology representing 8% of the total number of applications (European Patent Office, 2021; Medtech Europe, 2021). The medical technology industry in Europe employs around 760,000 people, with Germany having the largest share (Medtech Europe, 2021).

1.2 Medical device market in the Czech Republic

Unfortunately, aggregate data for this industry is not publicly available. Thus, several sources of information were used to summarise the Czech environment. Specifically, we used data from The Association of Manufacturers

and Suppliers of Medical Devices (AVDZP), the Register of Medical Devices (RZPRO), financial indicators from the Albertina database, and the PatentInspiration web application.

According to data from Patentinspiration.com (2021), members of the AVDZP had 448 active patents in the medical device sector as of November 30, 2020. As for employment, the medical device industry in the country employed over 10,266 people as of the same date, with large enterprises employing 7,370 people, almost 72% of the total. There were 105 member companies in the AVDZP, with small enterprises being the most numerous (41.8%). The Czech market segment of medical devices and in vitro diagnostics was estimated at USD 1.48 billion in 2016 by Emergo (2022), which was relatively small compared to other European markets. In terms of market value per capita, the value in the Czech Republic was USD 140, while it is USD 315.7 in Germany, USD 205 in France, and USD 160 in Great Britain. The Czech Republic had a slightly negative medical device trade balance of EUR 1 million in 2020, with exports reaching a value of EUR 1.194 million and imports amounting to EUR 1.195 million (Medtech Europe, 2021).

2. Research methodology

This part of the article describes the methodology used for the research. The study's design, data collection through a questionnaire survey and data processing are described. Furthermore, research limitations that we are aware of are mentioned.

2.1 Design of the study

As stated in the Introduction, this paper aims to evaluate the impact of newly effective regulation on the medical device industry in the Czech Republic using selected, primarily economic, and operational indicators.

Data from the Albertina database were used for this study, plus a questionnaire survey was conducted among companies (natural persons and legal entities) registered as importers, distributors, or manufacturers of general medical devices in the Czech Republic. Companies registered with contact details in the databases of the AVDZP and the State Institute for Drug Control served as the initial sample (N = 3,053). Due to budget constraints, we aimed to collect 100 completed questionnaires, resulting in a sample set of 100 (n = 100). A new subject was randomly selected if any questionnaires were identified as incorrectly filled in. A total of 139 completed questionnaires were randomly selected from the initial sample from August to October 2021. After excluding forty questionnaires for various reasons, such as incomplete or incorrect responses, too young entities (founded within the last two years), entities producing only one medical device, or entities not obligated to notify products of risk class I in the RZPRO database, the final research sample consisted of ninety-nine business entities.

The questionnaire was designed based on established research questions stated in the introduction of this paper. Like other projects using a questionnaire for data collection, we carefully considered the number and sensitivity of questions regarding company information. The research questions are now elaborated into the hypotheses below. Q in parentheses denotes questionnaire question number. Variable in relationship depends on secondary data. The questionnaire is included as an Appendix.

H1: The effects of regulation in terms of the product portfolio, innovation activities, and management do not depend on the size of the company (Q11 vs. size; Q13 vs. size; Q17 and Q18 vs. size).

H2: The capability to transfer the effects of MDR in the form of increased costs on customers does not depend on the size of the company (Q20 vs. size).

H3: The satisfaction of companies with the form of MDR does not depend on the size of the company (Q27 vs. size).

H4: The expected impact on profit does not depend on the expected impact on costs (Q17 vs. Q18 – verifies match with Q20 vs. size).

H5: The expected impact on profit does not depend on the capability of shifting regulatory costs on customers (Q18 vs. Q20).

H6: Product portfolio change does not depend on the perception of the impact on the economic performance (costs, profit) (Q11 vs. Q17 or Q11 vs. Q18).

H7: The decision to stop manufacturing a product does not depend on the 3-year trend of operating results (Q11 vs. profit trend).

H8: The decision to stop manufacturing a product does not depend on the 3-year trend of debt (Q11 vs. debt trend).

H9: The extent of the perceived impact of MDR on the company's costs does not

depend on the extent of the company's linear trend line of debt.

H10: The number of medical devices that are subject to conformity assessment or that already have to meet the requirements of MDR or for which the company participates in clinical evaluation does not depend on the expected impact on the company's costs or profit (Q5 or Q7 or Q9 vs. Q17 or Q18).

H11: The perception of MDR as an impetus for innovative activity does not depend on the expected economic impacts (costs, profit) (Q17 or Q18 vs. Q13)

H12: The company's satisfaction with the form of MDR does not depend on the perceived impacts on cost or profit (Q27 vs. Q17 or Q18).

H13: Product portfolio change does not depend on the perception of MDR as an impetus for innovation (Q11 vs. Q13).

H14: Product portfolio change does not depend on the perceived satisfaction with MDR (Q11 vs. Q27).

H15: The impact of the regulation in terms of the product portfolio does not depend on the number of medical devices that are subject to conformity assessment or already have to meet the requirements of the MDR or for which the company participates in clinical evaluation (Q11 vs. Q5, Q7, Q9).

H16: The company's satisfaction with the form of MDR does not depend on its perception of MDR as an impetus for innovation (Q13 vs. Q27).

As can be seen from the hypotheses, the questionnaire focused on questions concerning the production itself (number and structure of products) and economic and financial matters and impacts. In terms of the economic process, we were also interested in the impact of MDR on innovation activity.

Some hypotheses we have established tested the independence of primary data from questionnaire surveys and secondary economic data from the Albertina database for 2018–2020, before the introduction of MDR. We considered a three-year period to eliminate the subjective perception of the situation due to the impending effective date of MDR. Due to the availability of economic data only for entities obligated to publish financial statements under Czech legislation, the research sample was narrowed down from ninety-nine subjects to forty-two subjects with "financial statements in full" available, per Czech accounting legislation requirements. These financial statements in full include balance sheet and income statements (i.e., structured data on assets, owner's equity, liabilities, revenues, expenses/costs, and profit/loss).

2.2 Data collection – questionnaire survey

A pilot verification of the functionality of the questionnaire preceded the survey itself. In cooperation with AVDZP, eighteen completed questionnaires were obtained as part of the preliminary research. The collected surveys contributed feedback on the basis of which the questionnaire underwent minor modifications with the aim of increasing its return through comprehensibility and convenience of filling and, above all, its usability for the subsequent data analysis. Changes to the questionnaire did not hinder the applicability of the completed questionnaires for the overall evaluation, and these questionnaires were also used in the overall assessment.

Considering the research objective, the questionnaire was divided into the following thematic areas:

- The company's basic characteristics and product portfolio;
- The company's perception of the effects of regulation on the internal operation of the company (portfolio, personnel, financial resources, and management);
- The company's performance based on economic indicators;
- The company's perception of the impact of regulation on the general development of the market for medical devices;
- During data collection, we aimed primarily at CEOs and CFOs to prevent potential research limiting factors such as respondents with limited knowledge of the company's processes.

2.3 Statistical processing

In the Results section of this paper, descriptive characteristics are presented, including absolute and relative frequencies, measures of location (e.g., arithmetic mean, median), and variability (standard deviation).

The tested hypotheses were previously presented in the study design section. Given the categorical or ordinal nature of the data, the non-parametric Spearman's rho correlation

coefficient was calculated to verify the (in)dependence of relationships between variables, considering the importance of their order over their values. IBM SPSS Statistics 28 program was used for calculations.

3. Results

This chapter first presents the basic business characteristics of the research sample. These characteristics affected data availability and collection (business legal form). Product portfolios are then discussed. A quantitative evaluation of the questionnaire is presented, followed by economic indicators of surveyed companies. The chapter concludes with an analysis of the relationships between questionnaire data and financial/economic data.

3.1 Characteristics of the research sample

As stated in the previous chapter, 139 responses were initially obtained through the questionnaire survey. After excluding forty questionnaires (for exclusion criteria, see chapter 2.1), the sample was reduced to ninety-nine responses from business entities operating in the medical device sector. The following paragraphs present characteristics that tend to significantly influence the results of questionnaire surveys in enterprises, such as the business's legal form, the business, the business's size, and the product portfolio's structure.

The legal form of business

Regarding the legal form of businesses, two respondents are self-employed, eighty-nine are limited liability companies, eight are joint-stock companies and zero others (i.e., limited partnership or general partnership).

Size of businesses

Regarding business size, the sample consisted of four (4.04%) large enterprises, thirteen (13.13%) medium enterprises, forty-three (43.43%) small enterprises, and thirty-nine (39.39%) microenterprises, based on the EU classification for enterprise size. The majority of the sector is comprised of small and medium-sized enterprises (SMEs).

As per Czech accounting legislation, the legal form of business and size of the company affected the availability of financial and economic data in subsequent analysis steps. Therefore, the research sample had to be reduced in some analysis steps to maintain objective economic perspectives (indicated below when applicable).

Product portfolio

The composition of the company's product portfolio is one of the most important characteristics with regard to the focus of the research. Tab. 1 shows that 46% of respondents are manufacturers, with class I medical devices most represented (33%), followed by IIa and IIb (15% and 14%, respectively). Only 21% of companies do not operate as distributors, with IIa and IIb devices most abundant in distribution. Sixty percent do not act as importers, and IIa and IIb devices are most represented in imports.

Tab. 1: Classes of medical devices in the surveyed companies

	I am not M/D/IMP	I	Im	Is	IIa	IIb	III	IVD
Manufacturers (%)	54	**33**	3	2	15	14	6	1
Distributors (%)	21	36	0	1	**59**	46	21	2
Importers (%)	60	15	0	0	**33**	28	8	1

Note: I am not M/D/IMP – such a company does not have a product in its portfolio that would place the company in the category manufacturer (M)/distributor (D)/importer (IMP); companies can have two or more roles, so the column total may not add up to 100%.

Source: own

The medical device companies in our research sample are primarily small or micro-sized limited liability companies acting as distributors for class IIa medical devices. Manufacturers, among them, mainly produce class I medical devices.

Financial characteristics

Because only forty-two out of ninety-nine business subjects had complete data available in

the Albertina database comprising financial statements from 2018 to 2020 (see more in the section on the design of the study above), the description of the financial characteristics of the research sample is limited.

Since the article focuses on the economic impacts of MDR, costs (the dominant consideration in relation to regulation), profit, profitability, and selected financial health indicators are commented on in the medium term before the MDR comes into effect.

The costs of analyzed enterprises constantly grew, reaching CZK 9.42 billion (EUR 366.8 million) in 2018 and CZK 11.27 billion (EUR 425.3 million) in 2020. Costs per average company were CZK 224.3 million (EUR 8.73 million) in 2018 and CZK 268.2 million (EUR 10.12 million) in 2020, with the median enterprise having costs of CZK 77.7 million (EUR 3.03 million) in 2018 and CZK 94.5 million (EUR 3.57 million) in 2020. The annual growth rate of costs for all forty-two companies accelerated from 3.82% in 2018/2019 to 15.20% in 2019/2020.

Operating profit, which is not affected by financing methods, decreased by 21.26% between 2018 and 2019 but revived in 2020 with a profit growth rate of 198.82%. The average company achieved an operating profit of CZK 21.25 million (EUR 0.83 million) in 2018 and CZK 50 million (EUR 1.89 million) in 2020. In 2020, seven enterprises were loss-making, and the monitored forty-two companies achieved an operating profit of CZK 2.1 billion (EUR 79.25 million) together.

Both the return on equity (ROE) and return on sales (ROS) indicators inherently track profit development (despite the fact that only operating profit development is presented above, while ROE is calculated from EAT). The average and median values for 2018–2020 are shown in Tab. 2.

Tab. 2 shows that ROE reaches about 20% for average values, except in 2019. The median ROE grew significantly in 2020. In 2020, ROS brought in slightly over CZK 0.06 of profit per CZK 1 of sales. Standard deviation increased

Tab. 2: ROE and ROS profitability indicators in 2018–2020 (*n* = 42, or 40*)

Year		2018	2019	2020
ROE (%)	Average company	19.31	14.38	22.28
	Median company	8.94	8.02	20.20
ROS* (%)	Average company	5.31	3.83	6.37
	Median company	3.06	3.11	6.47

Note: *Two companies were discarded as outliers due to extreme values.

Source: own

Tab. 3: Indebtedness and financial health indicators in 2018–2020 (*n* = 42)

Year		2018	2019	2020
Indebtedness (%)	Average company	41.34	43.06	43.88
	Median company	41.12	42.78	41.52
Taffler	Average company	1.08	0.85	1.37
	Median company	0.65	0.69	0.84
Index IN99	Average company	1.44	1.21	1.40
	Median company	0.99	0.90	1.17

Note: Taffler > 0.3 low probability of bankruptcy of the company; IN99 from the interval [1.42, 2.07] – the business creates value for the owner; IN99 from [1.089, 1.42] – it is not possible to determine whether or not the business creates value for the owner; only intervals important for the interpretation of the table are given in the note.

Source: own

for ROE and ROS in 2020, indicating growing business performance disparity. See Tab. 3 for the development of the indebtedness indicator, representing financial stability and health via the bankruptcy/creditworthiness model.

The average and median indebtedness values are similar. Businesses are not generally over-indebted (the 2020 standard deviation is 42.54, dropping to 28.37 after removing an extreme value of 248.82). Taffler's model shows low bankruptcy probability for most companies, with only three having increased risk (Taffler < 0.2). The Index IN99 suggests that it is uncertain whether businesses are creating value, with 16 (38% of the sample) creating little to no value (IN99 < 1.089).

The sample displays positive financial characteristics, with profitable, stable, and minimally indebted enterprises. Unless significantly affected by MDR, their existence should not be threatened.

3.2 Innovation activity and perception of the impact of regulation on the development of medical devices

Virtually every industry regulation impacts businesses in that industry or closely connected ones. History shows regulations can have positive/negative effects on innovation (Maresova et al., 2020). In the questionnaire, we asked about the impact of MDR on innovation. Tab. 4 shows most respondents (57.58%) view MDR as an innovation obstacle. However, 36.36% say MDR has no effect, and only 6.06% see it as an innovation impulse.

From Tab. 4, it is evident that the majority of surveyed businesses are dissatisfied with the MDR (29.29% somewhat dissatisfied and 26.26% very dissatisfied, totalling 55.55%). About 35.35% of respondents did not have an opinion on the form of MDR at the time of the survey, and only 9.09% were somehow satisfied with the regulation.

There seems to be an overlap between innovation activity and satisfaction with MDR, indicating a potential dependence (further explored in chapter 3.4 through statistical testing). Before delving into the testing, the article examines selected procedural and economic questions considering that the company's financial situation may affect the perception of MDR (independence testing to be discussed in chapter 3.4).

3.3 Procedural and economic impacts

We begin this chapter by looking at procedural matters significantly related to the effectiveness of MDR. Specifically, we focus on the involvement of a specialist in dealing with the regulatory requirements of MDR during the development of a new product (see questions Q22 and Q23 in the questionnaire; presented in Tab. 5).

From Tab. 5, it can be seen that most often, the surveyed companies did not create a new position due to MDR, or they already had such a person for the needs of MDD – Medical Device Directive (40.40%). On the other hand, roughly half of the companies (50.50%) created such a new position in some variant.

Concerning the inclusion of a regulatory specialist in the project development team, the results show a division of companies into two roughly equal-sized groups. While the first one involves the regulator specialist immediately when creating a team, the second group chooses a riskier path, where the regulator

Tab. 4: Partial questionnaire survey results for questions focused on innovative activity and satisfaction with the form of the new regulation

Q13	**MDR & innovation activity (%)**				
	Activity postponement	**Without influence**	**Impulse**		
	57.58	36.36	6.06		
Q27	**Level of satisfaction with regulation (%)**				
	Definitely not satisfied	**Rather not satisfied**	**Neutral**	**Rather satisfied**	**Definitely satisfied**
	26.26	29.29	35.35	7.07	2.02

Source: own

Tab. 5: Survey results – questions focused on procedural and economic impacts

Q22	Creation of a new external or internal position (%)							
	Yes. One internal	Yes. One external	Yes. One, internal-external combination	Yes. Two or more internal	Yes. Two or more external	Yes. Two or more, internal-external combination	No. We already have for MDD	I do not know. I cannot judge
	23.23	11.11	5.05	5.05	0	6.06	**40.4**	9.09
Q23	Involvement of the regulatory specialist in the team (%)							
	Immediately at the beginning (automatically)	Only when necessary	We do not engage					
	52.53	26.26	21.21					
Q11	Removal of product from portfolio due to MDR (%)							
	Definitely not	Rather not	I do not know now	Rather yes	Definitely yes			
	18.18	18.18	22.22	13.13	**28.28**			
Q15	Impact of MDR on funding sources and opportunities (abs. values, selected as a true statement for the business)							
	Negative influence	Increased costs limit the possibility of innovation	Financial resources are readily available	Without influence	Neither is true for us			
	45	**47**	5	31	5			
Q17	Estimated impact of MDR on costs growth (%)							
	Very weak	Weak	Moderate	Strong	Very strong	No effect		
	10.20	20.41	**28.57**	10.20	15.31	15.31		
Q18	Estimated impact of MDR on profit (%)							
	Definitely negative	Rather negative	Neutral	Rather positive	Definitely positive	No effect		
	28.57	31.63	**36.73**	3.06	0.00	0.00		
Q20	Ability to pass on increased costs to customers (%)							
	Definitely no ability	Rather no ability	I do not know	Rather able	Definitely able			
	24.49	**33.67**	31.63	7.14	4.08			

Source: own

specialist is only involved when there is a problem or not at all.

The last of the procedural questions addressed in our questionnaire was the question of possible changes to the product portfolio concerning MDR (see Q11 in Tab. 5). It can be stated that MDR will impact the product portfolio, which will be narrowed, in 41.28% of companies. This means that MDR will force a certain part of medical devices out of the market, which can mean both a reduction in supply and a price increase. From this point of view, MDR can be viewed negatively.

We will now focus on economic issues (Q15, Q17, Q18, and Q20 in Tab. 5 and Q25). New regulations often bring about negative and positive changes, including the company's economy. For MDR, expected increased costs (confirmed by Q17 when the majority of companies (85%) perceive increased costs) may lead to reduced profitability (actually quite confirmed by Q18 – approximately 60% estimate negative impact) and longer return on investment periods. This may impact funding willingness. The assumption is quite confirmed by Q15, with nearly 50% of respondents indicating a negative impact on financing, while about 31% report no impact. Increased costs also limit innovation activity in the case of almost 50% of enterprises. In addition to that,

26% face limitations in innovative activity and at the same time, these feel financing constraints. Finally, over half cannot transfer costs to customers (Q20), which roughly corresponds to the expected negative impact on companies' profits (Q15).

Lastly, Q25 evaluates investment activities, but as respondents could select multiple answers, the total number of respondents does not match the sum of answers. The involvement of any of the methods is essential for business planning and attracting venture capital (Markiewicz et al., 2017). And this research tells us how detailed the examined companies can assess the economic impacts of the MDR.

Over 25% of enterprises do not use any investment evaluation method (likely relying on ad hoc evaluation). Moreover, 30% of respondents may have been influenced by the role or knowledge of the terminology of the person filling out the questionnaire rather than reflecting on the company's practices. Other companies use both static and dynamic methods for evaluating investment effectiveness. Most businesses rely on a single method. The static ROI method dominates. Applying static methods is typical for SMEs, which were the most numerous in our research sample. However, research by Craven et al. (2012) shows that a systematic approach to these methods can benefit manufacturers concerning customers, especially in the medical device sector.

3.4 Evaluation of the impact of regulation on the sector

This chapter is based on data from our own questionnaire survey and economic data from the Albertina database.

The first four parts of the results below provide an overview of the interrelationships between the questionnaire responses. The final, fifth part reveals the relationships between the questionnaire survey data and economic data from companies' financial statements.

For statistical processing, 99 questionnaires (n = 99) were initially used to test relationships between variables from the questionnaire survey. After including economic data for the second part of the results (the final fifth part), forty-two subjects and their questionnaires were used. The sample size reduction was necessary mainly due to the public availability of economic data, which some entities were not obligated to disclose (e.g., self-employed individuals), or had limited obligation (e.g., micro and small accounting entities), or had not yet held general meetings, or did not comply with the obligation due to considering their company information private (e.g., some companies in the Czech Republic prefer paying fines over providing the information).

Selected impacts of regulation with respect to company size

This section focuses on hypotheses *H1–H3*, examining the relationship between company

Tab. 6: Relationship between company size and selected criteria (n = 99; hypotheses *H1–H4*)

	Q11 The effects on product portfolio	**Q13** Viewing MDR as a driver of innovation	**Q17** Perception of effects on costs	**Q18** Perception of effects on profit	**Q20** Capability to transfer increased costs to customers	**Q27** Satisfaction with the form of MDR
Correlation coefficient	0.164	−0.054	−0.006	0.009	−0.167	0.010
Sign.	0.105	0.595	0.953	0.933	0.099	0.921

Note: Significant at *p > 0.05, **p > 0.01, ***p > 0.001, otherwise insignificant; Q – question.

Source: own

size and the impacts of regulation. Specifically, the effects on product portfolio (Q11), capability to transfer increased costs to customers (Q20), perception of impact on costs and profit (Q17 and Q18), and satisfaction with the form of MDR (Q27). The assumption is that larger companies may perceive impacts more leniently due to greater resources. Results are presented in Tab. 6.

It is clear from Tab. 6 that the company size does not influence the perceived impacts. I.e., the given test cannot reject the hypothesis of independence between the given variables. The result can therefore be interpreted so that the size of the company does not bring any advantages or disadvantages in terms of MDR concerning profit (Q18), costs (Q17), or the ability to pass on increased costs to customers (Q20). The size of the company does not lead to different attitudes, for example, to removing a product from the portfolio (Q11), to viewing MDR as a driver of innovation (Q13), or to being satisfied with the form of MDR (Q27).

Selected impacts of regulation concerning perceived economic (financial) impacts

Economic or financial impacts were the subject of questions Q17 (MDR impact on costs), Q18 (MDR impact on profit), and Q20 (ability to transfer costs to customers).

We tested the relationship between perceived impacts on costs and profit to verify answers to question Q20 (hypothesis *H4*). We also tested the relationship between perceived impacts on profit and the ability to transfer costs to customers (*H5*). The relationship between costs or profit and the decision to modify the product portfolio was also tested (*H6*). Hypothesis *H10* examined the relationship between the number of medical devices subject to conformity assessment (Q5), those already under MDR (Q7), or for which the company is involved in the clinical evaluation or PMCF (Q9), and perceived cost impacts (Q17). Finally, a two-way dependence was tested between perceived impacts on company management (Q17 and Q18) in relation to the perception of MDR as an impetus for innovative activity (*H11*) or perceived satisfaction with the form of MDR (*H12*). Hypotheses *H7–H9* are not included here and will be presented separately due to the limited availability of accounting data, as explained in the research methodology.

Cost, profit, and the ability to pass costs on to customers. *H4*: Hypothesis of independence between perceived cost change and profit change is rejected at $\alpha = 5\%$ (p-value < 0.001, correlation coefficient = −0.662; $N = 99$). Costs and revenues strongly correlated with negative dependence but not close to −1, indicating not all increased costs are reflected in profit. *H5*: Hypothesis of independence between the ability to pass on costs to customers and perceived impact on profit is not rejected at $\alpha = 5\%$ (p-value = 0.120, correlation coefficient = 0.157). The test shows a statistically insignificant relationship. The ability to pass on costs to customers does not significantly affect the impact on profit. Thus, the reduction in the strength of the association in the case of *H4* cannot be convincingly explained by *H5*. The results for both *H4* and *H5* imply that increased costs due to MDR will be at least partially covered by manufacturers or distributors. The alternative of shifting costs to suppliers was not examined.

Cost, profit, and size or change of product portfolio. Testing hypothesis *H6* provides these results. At $\alpha = 5\%$, we can accept the alternative hypothesis indicating a statistically significant relationship between impact on costs/profit and decision to change product portfolio (costs: correlation coefficient = 0.327, $p < 0.001$; profit: correlation coefficient = −0.374, $p < 0.001$). Greater negative impact on costs/profit motivates product removal from a portfolio.

Product portfolio size impacted by MDR (questions Q5, Q7, Q9) and perceived impact on costs/profit (hypothesis *H10*) results are shown in Tab. 7.

It is apparent from Tab. 7 that, as far as costs are concerned, a statistically significant relationship is identified at the 5% level of significance between costs and the size of the product portfolio for medical devices subject to conformity assessment by a notified body or certification (Q5) and costs and the number of products for which the company actively participates in clinical evaluation or post-marketing clinical follow-up (PMCF; Q9). This relationship is indirect (correlation coefficient = −0.211 and −0.226, respectively). The indirectness of the relationship signals that some component of the costs will probably have a fixed character, which is diluted with the number of manufactured, distributed, or imported products among the total number.

Tab. 7: Relationship between product portfolio size affected by MDR and perceived cost or profit impacts (*n* = 99; hypothesis *H10*)

	Impact on costs (Q17) vs.			Impact on profit (Q18) vs.		
	Q5 How many MD are currently subject to conformity assessment	**Q7** How many MD are already subject to the requirements MDR	**Q9** For how many MD do you actively participate in clinical trials	**Q5** How many MD are currently subject to conformity assessment	**Q7** How many MD are already subject to the requirements MDR	**Q9** For how many MD do you participate in clinical trials
Correlation coefficient	−0.211	−0.191	−0.226	0.118	0.026	−0.236
Sign.	0.036*	0.059	0.024*	0.244	0.798	0.018*

Note: Significant at *p > 0.05, ** p > 0.01, *** p > 0.001, otherwise insignificant; Q – question.

Source: own

In contrast, for the number of medical devices that already must meet the requirements of MDR, the hypothesis of independence from a perceived impact on costs cannot be rejected (p-value > 0.05). For the relationship between profit and the number of medical devices, the hypothesis of independence can be rejected only for medical devices for which the subject participates in clinical evaluation or PMCF (see Q18 vs. Q9 in Tab. 7). That is, the more medical devices with this characteristic, the worse the impact on the company's profit. It is interesting, however, that for Q9, the direction of dependence expressed by Spearman's rho is negative for both costs and profit.

Cost, profit, and perception of MDR as an impetus for innovation. Hypothesis *H11* tested the independence between the perception of MDR for innovation activities and the perceived impact on the company's management in terms of costs and profit. Based on the results, it can be stated that the higher the costs related to the introduction of MDR, the lower the innovation activity (correlation coefficient = −0.559, p < 0.001). At the same time, the above-confirmed relationship also holds true that the worse the impact on profit, the worse the perception of MDR as an impetus to innovative activity (correlation coefficient = 0.533, p < 0.001).

Overall, it can be concluded that companies had to or still have to cope with the economic impacts of MDR and adapt their innovation activity accordingly.

Cost, profit, and satisfaction with MDR. In establishing hypothesis *H12*, it was assumed that the economic view associated with higher costs or lower profit levels connected with MDR would influence satisfaction with this regulation. Test results show a significant link between increased costs (or negative impact on profit) and satisfaction with MDR, with a correlation coefficient of −0.437 (p-value < 0.001). In other words, the stronger MDR influences perceived cost growth, the lower the satisfaction with MDR. Similarly, the negative link between profit and satisfaction was confirmed, with a correlation coefficient of 0.533 (p-value < 0.001). This means that a higher negative impact on profit resulted in lower satisfaction with MDR. These findings shed light on the prevailing dissatisfaction with MDR found in the questionnaire survey, where 56.25% of respondents were rather dissatisfied or very dissatisfied with MDR (Q27), and 33.93% were neither satisfied nor dissatisfied. Additional observations from open question Q28 revealed that respondents often perceive administrative or bureaucratic requirements as burdensome, which may

equate administration with costs and further influence satisfaction with MDR.

Selected impacts of regulation regarding product portfolio reduction as a response to MDR

This section evaluates hypotheses *H13*, *H14*, and *H15*. First, *H13* tests the relationship between change in product portfolio and the perception of MDR as an innovation impetus (Q11 vs. Q13). The correlation coefficient is −0.339 (p-value < 0.001), suggesting that a lower perception of MDR as an innovation impetus is associated with higher readiness to withdraw a product from the existing portfolio. However, it should be noted that over half of the respondents perceive MDR as a barrier to innovation (57.58%), while a significant number state that MDR does not affect their innovation activities (39.29%).

Hypothesis *H14* focuses on satisfaction with MDR (Q27) and portfolio change (Q11). The null hypothesis of independence between satisfaction with MDR and portfolio change is rejected at the 5% significance level (p-level = 0.014, correlation coefficient = −0.246), indicating a link between the two phenomena. This suggests that as satisfaction with MDR decreases the number of companies that will change their product portfolio increases. In other words, dissatisfaction with MDR may arise from the need to intervene in the product portfolio due to new regulatory requirements.

Hypothesis *H15*, which examines possible changes in the product portfolio in relation to MDR, is not rejected. The null hypothesis suggests no significant link between the narrowing of the product portfolio and the number of medical devices subject to conformity assessment (Q5), or already meeting MDR requirements (Q7), or for which the company participates in clinical evaluation or PMCF (Q9), as presented in Tab. 8.

The results show that the number of manufactured, distributed, or imported medical devices does not seem to influence the decision to narrow the product portfolio. It cannot be said, for example, that with the increasing number of manufactured, distributed, or imported medical devices, the probability of withdrawing a medical device from the portfolio due to MDR would increase.

Impacts of regulation in the form of perceived satisfaction with MDR

The last tested hypothesis (*H16*) showed a statistically significant relationship between perceived satisfaction with MDR and MDR as an initiator of innovative activities. Spearman's rho value of 0.481 at the 1% significance level indicates a direct relationship. Specifically, as satisfaction with MDR decreases, the perception of MDR as an initiator of innovation activities also decreases.

Perceived satisfaction was also examined (see above) concerning company size (no relation), the decision to narrow the medical device portfolio (decreasing satisfaction leads to higher willingness to reduce portfolio), and perceived impacts on costs or profit (satisfaction decreases with increasing impact on costs and adverse impact on profit).

Tab. 8: Relationship between product discontinuation and selected criteria (n = 99; hypothesis *H15*)

	Exclusion of the product from the portfolio (Q11) vs.		
	Q5 How many MD are currently subject to conformity assessment	**Q7** How many MD are already subject to the requirements MDR	**Q9** For how many MD do you actively participate in clinical trials
Correlation coefficient	0.013	−0.007	0.106
Sign.	0.896	0.949	0.295

Note: Significant at *p > 0.05, **p > 0.01, ***p > 0.001, otherwise insignificant; Q – question.

Source: own

Data from financial statements versus answers from questionnaires

The last part of the research results section examines the relationship between financial data from surveyed companies' statements and questionnaire survey data. Specifically, it tests the link between the decision to drop a medical device from the product portfolio due to MDR and the 3-year trend of operating profit or indebtedness (*H7* and *H8*). In terms of operating profit and product removal, no proven connection is found, and the hypothesis of independence cannot be rejected (p-value > 0.05). However, when the trend of indebtedness is considered, a statistically significant relationship emerges (Spearman's rho = −0.347, p-value = 0.024). Companies in debt are more inclined to exclude products from the portfolio. Finally, the declared effect of MDR-related business costs (Q17) in relation to the debt trend (*H9*) shows no proven dependence, and it is unclear if companies spread their MDR costs over the previous three years or if the declared cost increase could influence the trend.

4. Results summary and discussion

The perceived cost increase caused by MDR is statistically reflected in the worsened business performance as measured by profit. Businesses, including manufacturers, distributors, and importers of medical devices, state their inability to shift the increased costs resulting from MDR to their customers, leading to a negative impact on profit. However, this view of the companies, specifically the link between the (in)ability to transfer costs to customers and the negative impact on profit, is statistically insignificant. The impacts of regulation are perceived similarly by all businesses, irrespective of their size.

Satisfaction with the form of MDR is low, with 56.25% of respondents expressing dissatisfaction and 33.93% indicating neutrality. Our survey results indicate dissatisfaction is primarily connected with the need to change product portfolios and increased costs, which respondents often identify as an administrative burden. Therefore, the challenge for future work with MDR is to focus on measures that address administrative steps and minimise administrative burden as much as possible. Historical evidence shows that rising costs and risks adversely impact the development and launch of new products (Grabowski et al., 1978).

Tab. 9: Summary of responses to research questions

RQ1	**Does the company size affect the potential or perceived impacts of MDR on a company?**
	No, but the research sample is quite homogeneous. A high percentage of SMEs is represented.
RQ2	**Do economic conditions such as business performance or financial health influence the adaptation of processes with regard to MDR or the perception of MDR as such?**
	First of all, it can be stated that businesses mostly do not believe that they will be able to transfer MDR-related costs to customers, and increased costs will therefore translate into lower profits. The perceived negative impact on profit is accompanied by a reduction in the portfolio size.
RQ3	**Are the effects of MDR manifested in the product portfolio of companies?**
	Yes, but it does not depend on the size of the companies, but rather on the current perception of the impact of MDR on costs and profit (costs are increasing, profits are decreasing). The decision to remove products from the portfolio is not influenced by the previous medium-term trend of profit, but it is influenced by the change in indebtedness in the last 3 years before the MDR came into effect.
RQ4	**Can satisfaction with the form of MDR be an innovation impulse for medical device development?**
	Yes, it can. But this survey identified mostly dissatisfaction with MDR, which, as seen in the answer to *RQ2*, may stem from costly new requirements. The innovation impulse of MDR is, therefore, rather negative.

Source: own

Tab. 9 provides answers to the research questions formulated in the introduction of this paper with respect to the aim of the research.

The research findings indicate that businesses see increased costs and reduced profits as the effects of MDR. About one-third of companies also reduce their product portfolio in response to MDR. Carl and Hochmann (2023) also come to similar conclusions about the reduction of the product portfolio as an effect of MDR. With regard to the higher demands of the MDR (and the associated higher costs), Bayrak and Yilmaz (2022) caution that MDR may further strengthen the import position of countries already importing medical devices due to its strictness and increased costs for market actors.

Other notable findings unrelated to the research questions or tested hypotheses include the importance of regulatory specialists in the team and evaluating the economic effectiveness of investments. From this, one can infer the impact of MDR on company processes, the company's ability to respond to new MDR challenges, and the ability to economically assess MDR more in detail.

First, regarding the involvement of regulatory specialists, survey responses indicate that this role has gained greater importance in companies, with nearly 50% reporting the creation or strengthening of this position. About three-fifths of these roles are internal. Similar findings are seen in health technology assessment (HTA), as Markiewicz et al. (2017) noted. However, companies also state that they involve regulatory experts in project development teams only when necessary (26.26%) or not at all (21.21%). Scannell and Cormican (2019) recommend involving a regulatory expert early in developing new medical devices, even in spinoff scenarios. In any case, our results thus confirm the expectation (Becker et al., 2019) that MDR brings higher costs, e.g., through a higher workload.

Second, regarding the involvement of investment effectiveness evaluation methods, companies in our Czech research sample tend to use dynamic methods like net present value (NPV) less frequently compared to the Dutch research sample presented by Markiewicz et al. (2017). However, both samples show that the return on investment (ROI) method is commonly used. In our case, it is also appropriate to add that approximately 56% of businesses do not use any such method or are unaware of it.

Findings of the study develop previous studies such as Gozman and Currie (2014) describing how organizations are reviewing and altering the practices and systems employed to deliver compliance and how to ensure that new regulatory requirements are met within designated timeframes and managed on an ongoing basis. Other studies have broadly touched on compliance by addressing how specific legislation can be leveraged to add value, as well as making the case for a strategic approach to risk and compliance (Chatterjee & Milam, 2008). Our findings expand theories about knowledge from the medical device industry and open future questions in management and leadership. Effective leadership is a vital component of health care systems and has an extensive range of functions in improving organizational effectiveness and efficiency. It seems that the leaders of the institutions will have a significant role in the society's adaptation to the new setting.

One limitation of our research is the quantitative approach typical of questionnaire surveys. The identified links suggest the need for qualitative data, which could be obtained through structured interviews with a narrower panel of respondents in similar roles (e.g., CEO or CFO of the companies). Such an approach would help define MDR-related problems more precisely and enable further work within the regulatory framework. In addition, despite efforts to formulate questions clearly, illogical answers appeared, and reluctance to answer some questions was observed. In such cases, questionnaires had to be discarded. Another limitation is that distributors and importers may not perceive the impact of regulation on their role, leading to a lack of awareness of their obligations. Additionally, there is a disproportion between risk classes and company roles, as respondents are mostly distributors and importers of lower-risk class devices, limiting their ability to fully evaluate the regulation's impact on innovation and production.

In order to comprehensively describe the goal "to evaluate the impact of newly effective regulation on the medical devices industry," it is appropriate to extend the research to other European countries, ensure a longer time series of economic data, and the already mentioned additional qualitative research. Such research will then be able to assess the impact of regulation on the entire industry.

Conclusions

Implementing regulations is often seen as necessary to mitigate market failures and safeguard consumer interests. The Medical Device Regulation (MDR) is a recent European regulation specifically designed for the production of medical devices, aiming to ensure their safety and effectiveness. This article focuses on Czech companies and examines the MDR's effects on their operations regarding both economic and procedural impacts.

The findings of this research intimate that the MDR will negatively impact a company's profitability, consequently influencing its operational strategies, and are in line with the general expectations expressed, e.g., by Becker et al. (2019). In the case of the orthopedic aids sector, based on a two-year observation, Carl and Hochmann (2023) also highlight the negative impacts of MDR in the form of increased costs and a reduction in the product portfolio.

One key factor contributing to this negative outcome is the inability of the companies to transfer the increased costs resulting from regulatory requirements to their customers. As a result, affected companies are forced to adjust their product portfolios, reducing their range of offerings. The findings of this research show that approximately one-third of the research respondents (n = 99) declare that they will almost certainly discontinue one of the products from their current portfolio.

The research reveals that the perception of the MDR among medical device manufacturing companies is predominantly negative. A significant finding is almost 50% dissatisfaction with the form of MDR (approximately 35% perceive MDR neutrally). This negativity arises primarily due to the financial burdens imposed by the regulation and the other associated impacts.

Furthermore, the MDR is not perceived as a catalyst for innovation within the industry, as nearly two-thirds of companies report postponing innovation activity due to the MDR. Therefore, this may be detrimental to the end user in the long term.

By quantifying the effects of the MDR on Czech companies, this article provides valuable insights into the real-world implications of this regulatory framework. The findings highlight the challenges companies face in adapting to and complying with the MDR, particularly regarding its impact on profitability and product offerings.

This research serves as a reminder of the complex interplay between regulations, economic outcomes, and industry dynamics. Ultimately, it emphasizes the importance of considering the potential ramifications of regulations and their effects on businesses and markets. Undoubtedly, the MDR will improve safety, but at what cost? Some of the ramifications are highlighted in this article. There is, however, a need for debate on whether the current setting of risk elimination on the one hand and costs and restrictions on the other is really beneficial to either the consumer or the manufacturer. This article is timely as it addresses an important current topic of debate and seeks to fill a gap in the literature.

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Appendix

Questionnaire (list of questions)

- Q1. Company name
- Q2. Medical device class(es) – production
- Q3. Medical device class(es) – distribution
- Q4. Medical device class(es) – import
- Q5. How many medical devices manufactured/distributed/imported by you are currently subject to conformity assessment by a notified body or certification?
- Q6. Which class?
- Q7. How many medical devices manufactured/distributed/imported by you are already subject to the requirements of the new medical device regulation?
- Q8. Which class?
- Q9. For how many medical devices manufactured/distributed/imported by you do you actively participate in clinical trials or post-market clinical follow-ups?
- Q10. Which class?
- Q11. Are you planning to phase out any product from your portfolio due to the new regulation, even though you would not have done so under the old regulation?
- Q12. Why?
- Q13. Innovation with respect to the new medical device regulation: Do you see the new regulation as an impulse, obstacle, or irrelevant factor?
- Q14. Why?
- Q15. Financial resources and opportunities: Check all statements that are true for your business entity.
- Q16. Why?
- Q17. The new regulation has affected our financial indicators in terms of overall COSTS.
- Q18. The new regulation will affect our financial indicators in terms of overall PROFITS.
- Q19. Why?
- Q20. We are able to shift the increased costs associated with regulatory requirements on our customers.
- Q21. How/in what way? Or why not?
- Q22. Regarding the new regulation, did you have to create a new internal or external position for a person responsible for regulatory compliance (regulatory officer)?
- Q23. We usually involve an expert on regulatory issues in the project/development team.
- Q24. How/in what way? Or why not?
- Q25. Which indicators do you use to evaluate the contribution of the product to the overall performance of the company?
- Q26. If you use other indicators, which ones?
- Q27. To what extent is your company satisfied with the new medical device regulation?
- Q28. Which requirements of the new regulation do you perceive as the most burdensome/problematic? State up to three answers but at least one.
- Q29. Why?
- Q30. What do you consider the greatest LIMITATIONS of the new regulation? State up to three answers but at least one.
- Q31. What do you consider the greatest OPPORTUNITIES of the new regulation? State up to three answers but at least one.