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The impact of the European medical device regulations EU 2017/745 and EU 2017/746 on Business Management and Insights of the maturity of quality management systems of the organizations for regulatory purposes


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The impact of the European medical device regulations EU 2017/745 and EU 2017/746 on Business Management and Insights of the maturity of quality management systems of the organizations for regulatory purposes

The thesis examines the impact that adhering to the European medical device regulations EU 2017/745 and EU 2017/745 has on medical device manufacturers with focus on a business management and the development quality management systems for regulatory purposes. The objective was to explore the experiences and maturity levels of the organization to be complying with requirements related to manufacturer´s responsibility. Also, it provides an insight into how alignment to international standards enables organization to meet requirements by regulation.

This research was conducted to address the increasing demands placed on medical device manufacturers by evolving European legislation and to provide insights into how these demands influence organizational compliance efforts. Also to understand the implicit cost, maturity levels and have a better understanding of experiences and challenges of organizations.

The results demonstrate that organizations are adopting robust compliance strategies and have experienced significant improvements in their quality management systems, which leads to enhanced operational efficiency and market reputation. Compliance with EU 2017/745 and EU 2017/746 not only ensures product safety and effectiveness but also enables market access to all member states and export to third countries that recognize and trust the European CE marked products.

Keywords: Health Technology, European regulations, medical device, in vitro diagnostics, MDR, IVDR, Quality Management System, medical device manufacturer.

Content

Appendices

List of abbreviations (or) symbols

Abbreviation	Explanation of abbreviation
AHWP	Asian Harmonization Working Party
AMDF	African Medical Devices Forum
AR	Authorized Representative
ASEAN	Association of Southeast Asian Nations
DoC	Declaration of Conformity
DMAIC	Define-measure-analyze-improve and control
TDA	Technical Documentation Assessment
EU	European Union
IMDRF	International Medical Device Regulators Forum
ISO	Internation Standard Organization
IVD	*In vitro* Medical Device
IVDR	*In vitro* Diagnostic Medical Device Regulation
MD	Medical Device
MDR	Medical Device Regulation
MERCOSUR	Mercado Común del Sur
NB	Notified Body
QMM	Quality Maturity Model
QMMG	Quality Management Maturity Grid
QMS	Quality Management System

RAPS	Regulatory Affairs Professional Society
USMC	United States- Mexico-Canada Agreement
WHO	World Health Organization

1 Introduction

The European Union published in 2017 two regulations, Medical Devices Regulation (MDR, 2017/745) and In Vitro Diagnostic Medical Device Regulation (IVDR, 2017/746), which present stricter rules to place on the market, making available on the market or putting into service medical devices and accessories. The IVDR and MDR brought significant changes that impacted organizations at different levels. The implementation of these new rules requires changes in the management of businesses, including human resources, product lifecycle and supply chain (manufacturers, authorized representatives, distributors and suppliers), as well as the relationship with the Notified body to assess the conformity of the products and services to be placed in the European Union.

This thesis focuses on understanding the different implications that the medical technologies regulation brought to the manufacturer and have insight on the challenges, cost and management maturity levels to meet the demands required before placing a device into European market.

The aim of this thesis is to study and understand how the EU MDR and IVDR regulation impacted organizations business and management of medical devices companies (structures, processes and investments for example). Also, it explores the quality management system maturity for regulatory purposes of medical device companies.

The overview of the thesis divided into 5 phases 1) Studying and analyzing IVDR and MDR 2) Preparation of a questionnaire 3) Delivery of the questionnaire to target audience 4) Preparation and Analysis of results and 5) Preparation of thesis Discussion and Conclusions.

2 Literature Review

2.1 Global Outlook on Medical Device Industry

First, Health technologies like medical devices and *in vitro* diagnostics are important for a functional health system (WHO, 2022, Table 1). Second, Medical devices and *in vitro diagnostics* devices have different attributes and a wide variety of intended purposes like diagnostic, treatment, monitoring of diseases, they can save and improve people's lives (WHO, 2022). Third, Medical technologies could include products, services or solutions used to save and improve people´s lives and they are divided into three categories (Ritchey, 2021, Rohr *et al*, 2016, Mathews *et al*, 2019, WHO, 2022 MedTech Europe, 2025)

Table 1: *Characteristics of Medical Technology or Health Technology.*

Medical Devices (MDs) 	**In vitro diagnostics (IVDs)** 	**Digital health** 
MDs are products, services or solutions that prevent, diagnose, monitor, treat and care for people or alleviate health condition (Ritchey, 2021; MedTech Europe, 2025)	IVDs are non-invasive tests or in vitro tests used on biological samples (for example, whole blood, plasma, saliva, urine or tissues) to determine or monitor the status of a person's health or physiological status (Rohr *et al*, 2016; MedTech Europe, 2025)	Digital Health are tools and services that use information and communication technologies to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle. (Mathews *et al*, 2019; MedTech Europe, 2025)

Next, the stakeholders in Medical Devices Industry are patients, health care professionals, ethics committees, competent authorities, notified bodies, academic and nonacademic health institutions, customer, legal manufacturer, distributor,

contract research organizations, contract manufacturer (Woudstra et al, 2022, Agouridas, *et al* 2006, WHO, 2022). Other stakeholders can be considered the standardization organizations, economic operators (**Figure 2**), working groups established by the EU commission, industry representation like European Trade Associations (RAPS, 2022)

Also, the global medical device market size is valued at USD 542.21 billion in 2024 and the forecast for 2025 is to reach USD 572.31 billion. On the other hand, there is an expectation to increase up to USD 886.68 billion by 2032 with a compound annual growth rate (CAGR) of 6.5% between 2025-2032 (Fortune business Insight, 2025). There are three factors that influence this growth: The first one is the increase of patients experiencing acute and chronic diseases and the second one the availability of treatments options among patients and diagnostics tools due to innovations and the increase which lead to the rising number of diagnostics and surgical procedures. Among the divisions that show these increased the research center fortune business insight (2025) identifies devices in the categories: Orthopedic Devices, Cardiovascular Devices, Diagnostic Imaging Devices, In-vitro Diagnostic (IVD), Minimally Invasive Surgery Devices, Wound Management, Diabetes Care Devices, Ophthalmic Devices, Dental Devices, Nephrology Devices, General Surgery.

2.2 Market Dynamics

Medical Devices is part of the Healthcare Industry, Medical device industry is a very dynamic market, it faces different challenges, each country has its own regulatory environment, which poses a toll on organizations. This market is highly competitive and shows a fast regulatory evolving scenario. Next, the analyses of the market dynamics based on the five Porter´s forces (Porter, 2011, Maresova and Kuca, 2014) i) *Bargaining power of buyers.* Buyers, including healthcare service providers, hospitals, clinics have significant bargaining power because they purchase medical devices in large volumes and easily can switch the scenario that buyers have lower bargain power because of limited treatment options and

the critical nature of healthcare services (Maresova and Kuca, 2014) ii) B*argaining power of suppliers,* Suppliers in the healthcare industry have moderately to high bargaining power due to heavy reliance of the healthcare systems and high switching costs for patients. Also, due to the specialized nature of some device components and the regulatory requirements that limit the number of suppliers (Maresova and Kuca, 2014) iii) *Threat of new entrants, t*he threat of new entrants is influenced by high entry barriers such as regulatory requirements, the need for technological expertise, significant capital investments, intellectual properties and established brand loyalty (Maresova and Kuca, 2014). iv) *Threat of substitutes, t*he threat of substitutes is relatively low due to the specialized nature of some devices. If the devices had been already established for long time and the intellectual property rights expired, then there is risk of devices with same intended use that can be used as substitute if the devices have equal or better performance. (Maresova and Kuca, 2014) v) *Threat of rivalry, the c*ompetitive rivalry is intense, driven by the presence of numerous players in the market, technological advancements and the continuous need for innovation. (Maresova and Kuca, 2014)

2.3 Global overview of regulatory frameworks

The World Health Organization (2022) published global and national medical device situation in 194 countries, which profiles include medical devices policies, regulations, nomenclature and health technology assessment. This provides an overview of how highly regulated the medical device industry is. Manufacturers need to understand the regulatory framework and fulfill country-specific requirements for the product (See **Table 2**, **Figure 1**). During the last decade, most countries have been moving into harmonization of systems like application guidance, nomenclature or classification among other topics. For example, nomenclatures enable them to integrate information related to medical devices into databases for regulatory purposes, reimbursement, national lists inventory and procurement. A standard nomenclature system allows the manufacturer to identify the type and class of medical devices, making interactions easier. Nomenclature

systems are continuous and rapidly evolving depending on many factors, such as legislation, commerce, management, political will, economy, etc. Furthermore, manufacturers need to understand the regulatory framework in each region, including their nomenclature systems. Also, manufacturers need to take into account not only to country-by country analysis, but also the international or regional systems and guidances, such us: European Union, Southern Common Market (MERCOSUR), Association of Southeast Asian Nations (ASEAN), United States-Mexico-Canada Agreement (USMC), African Medical Devices Forum (AMDF) Asian Harmonization Working Party (AHWP) and International Medical Device Regulators Forum (IMDRF) (WHO, 2022). It is important to recognize the positive trend of countries to harmonize procedures and adopt more international nomenclature systems, which will in the long term will strength the health systems and provide faster health coverage (WHO, 2022)

Table 2: *Adapted list of regulatory authorities for 36/194 countries (WHO, 2022). The Regulatory authorities have a crucial role in overseeing the safety, efficacy and quality of medical devices across various regions. Each authority has their own procedures on how the regulatory framework is applied*

Country	**Regulatory Authority**
Austria	Federal Ministry of Social Affairs, Health Care and Consumer Protection Austrian Agency for Health and Food Safety (AGES) (for surveillance) Austrian Federal Office for Safety in Heatlthcare (BASG)
Belgium	Federal Agency for Medicines and Health Products (FAMHP)
Bulgaria	Bulgarian Drug Agency (BDA)
Croatia	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
Cyprus	Ministry of Health - Pharmaceutical Services
Czechia (Czech Republic)	State Institute for Drug Control (SUKL)
Denmark	Danish Medicines Agency
Estonia	State Agency of Medicines
Finland	Finnish Medicines Agency (FIMEA)
France	National Agency for the Safety of Medicine and Health Products (ANSM, *Fr. Agence Nationale de Sécurité du Médicament et des Produits de Santé*)
Germany	Federal Institute for Drugs and Medical Devices (BfArM) Federal Ministry of Health (MDR-IVDR Legislation)
Greece	National Organization for Medicines (EOF)
Hungary	National Institute of Pharmacy and Nutrition (OGYÉI)

Country	Regulatory Authority
Iceland	Icelandic Medicines Agenc
Ireland	Health Products Regulatory Authority (HPRA)
Italy	Ministry of Health
Latvia	State Agency of Medicines
Lithuania	State Health Care Accreditation Agency
Liechtenstein	Office of Public Health
Luxembourg	Ministry of Health
Malta	Malta Medicines Authority
Netherlands	Dutch Health Care Inspectorate (IGJ)
Norway	Statens legemiddelverk/ Norwegian Medicines Agency Norwegian Medical Products Agency, NoMA
Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Portugal	National Authority of Medicines and Health Products (INFARMED)
Romania	National Agency for Medicines and Medical Devices (NAMMD)
Slovakia	State Institute for Drug Control (SUKL)
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)
Spain	Spanish Agency of Medicines and Medical Devices (AEMPS)
Sweden	Medical Products Agency (MPA)
Turkey	Turkish Medicines and Medical Devices Agency (TITCK)
United States	Food and Drug Administration (FDA)
Russia	Federal Service for Surveillance in Healthcare (Roszdravnadzor)
European Union	European Medicines Agency (EMA)
India	Central Drugs Standard Control Organization (CDSCO)
South Korea	Ministry of Food and Drug Safety (MFDS)
Canada	Health Canada
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
Brazil	National Health Surveillance Agency (ANVISA)
China	National Medical Products Administration (NMPA)
Australia	Therapeutic Goods Administration (TGA)

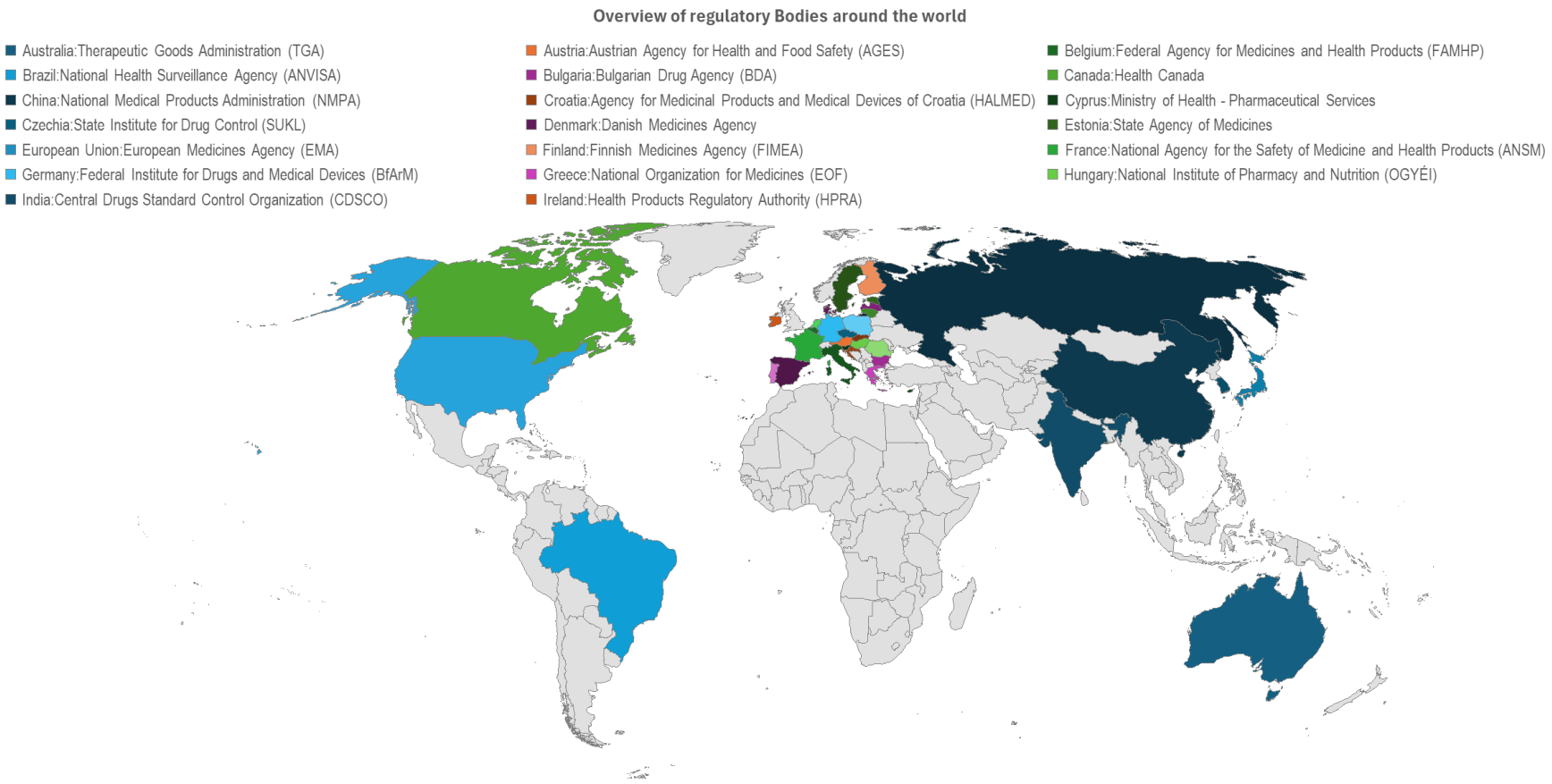

Figure 1: *Map providing information on 24 jurisdictions that have a regulatory framework for medical devices. Manufacturers need to establish a regulatory strategy that encompasses the markets where the product will be distributed and marketed (Prepared by Pérez-Gamarra, 2025).*

2.4 The European Union regulatory framework

The European Union (EU) is based on the rule of law. This means that every action taken by the EU is founded on treaties that have been approved democratically by EU members. The aim of EU laws is to achieve the objectives of the EU treaties and put the EU policies into practice. There are two main types of EU law, ***Table 3*** summarizes primary and secondary laws. (European commission, 2012) **Table 4** compares the types of legislative elements that European commission use and their purpose. Source: The treaty on the Functioning of the European Union (article 288, formerly article249 TEC).

Table 3: *Type of laws in the European union (*European commission, 2012).

Primary versus secondary law	**Legislative versus non-legislative acts**
• Every action taken by the EU is founded on the treaties. These binding agreements between EU member countries set out EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its members. • Treaties are the starting point for EU law and are known in the EU as primary law. • The body of law that comes from the principles and objectives of the treaties is known as secondary law; and includes regulations, directives, decisions, recommendations and opinions.	• Legislative acts are adopted following one of the legislative procedures set out in the EU treaties (ordinary or special). Non-legislative acts do not follow these procedures and can be adopted by EU institutions according to specific rules. • The EU can pass laws only in those areas where its members have authorised it to do so, via the EU treaties.

Table 4: *Different legislative elements in use in the European parliament.* Source: The treaty on the Functioning of the European Union (article 288, formerly article249 TEC).

EU treaties	Regulation	Directive	Decision	Recommendations and Opinions	Delegated Acts	Implementing Acts
The treaties lay down the objectives of the European Union, the rules for EU institutions, how decisions are made and the relationship between the EU and its member countries. The EU treaties have from time to time been amended to reform the EU institutions and to give it new areas of responsibility. They have also been amended to allow new EU countries to join the EU. The treaties are negotiated and agreed by all the EU countries and then ratified by their parliaments, sometimes following a referendum.	A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. Regulations are legal acts that apply automatically and uniformly to all EU countries as soon as they enter into force, without needing to be transposed into national law. They are binding in their entirety on all EU countries.	A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. Directives require EU countries to achieve a certain result, but leave them free to choose how to do so. EU countries must adopt measures to incorporate them into national law (transpose) in order to achieve the objectives set by the directive. National authorities must communicate these measures to the European Commission. Transposition into national law must take place by the deadline set when the directive is adopted (generally within 2 years). When a country does not transpose a directive, the Commission may initiate infringement proceedings.	A decision shall be binding in its entirety upon those to whom it is addressed. Decisions are binding legal acts that apply to 1 or more EU countries, companies or individuals. The party concerned must be notified and the decision comes into effect upon such notification. They don't need to be transposed into national law.	Recommendations and opinions shall have no binding force. Recommendations allow the EU institutions to make their views known and to suggest a line of action without imposing any legal obligation on those to whom it is addressed. They have no binding force. An 'opinion' is an instrument that allows the EU institutions to make a statement, without imposing any legal obligation on the subject of the opinion. An opinion has no binding force.	Delegated acts are legally binding acts that enable the Commission to supplement or amend non−essential parts of EU legislative acts for example, in order to define detailed measures. They are the WHAT. they represent an explicit decision to act on a certain issue. The Commission adopts the delegated act and if Parliament and Council have no objections, it enters into force. In other words, delegated acts become part of the legislation.	Implementing acts are legally binding acts that enable the Commission – under the supervision of committees consisting of EU countries' representatives – to set conditions that ensure that EU laws are applied uniformly. They define HOW the legally binding acts should be implemented. They provide procedures, deadline or templates for practical implementation of the rules in the original legislation.

2.5 European Medical Device Regulatory Framework

The European Medical Device regulatory framework consists of two regulations one for medical devices (MDR, 2017/745) and in vitro diagnostic medical devices (IVDR, 2017/746), which aim to be a “robust, transparent, predictable and sustainable regulatory framework that ensures a high level of safety and health while supporting innovation”. The European regulations presented several changes, for example: i) Stricter control to high-risk devices before they are placed on the market. ii) The inclusion of certain aesthetic devices with similar characteristics and risk to medical devices. iii) A new risk classification system for *in vitro* diagnostic devices, following international guidance (IVDR, 2017/746). iv) To have transparency through an EU database on medical devices (EUDAMED) and traceability based on Unique Device identification (UDI). v) The introduction of an “implant card” that contains the information of implanted medical devices to a patient (MDR, 2017/745) vi) The reinforcement of rules on clinical evidence, including a European wide coordinated procedure for authorization of multi-center clinical investigations. vi) More requirements on post-market surveillance. vii) Improved coordination mechanism between EU members on Market surveillance and vigilance.

2.5.1 IVDR and MDR Regulation Comparison

IVDR and MDR are sister regulations with similar construction. Both regulations drive general safety and performance requirements and allow CE Marking as an indicator that a product or service meets the MDR/IVDR requirements. Only devices complying with the regulations and applicable directives can apply mandatory CE Marking. Under both regulations, the Legal manufacturer, the Authorized representative (if the Legal manufacturer is not established in the European Union) and other economic operators have prescriptive responsibilities (IVDR, 2017 and MDR, 2017). In brief, the legal manufacturer must determine the risk classification of the device and implement requirements for the quality management

system (QMS). Prepare technical documentation according to IVDR/MDR annex II and III. Proceed to the conformity assessment, the conformity assessment can be self-conducted by the legal manufacturer for IVD classes A (non-sterile) and MD class I (non-sterile, non-measuring, non-reusable surgical instrument. Whereas the conformity assessment requires Notify Body (NB) involvement to audit the QMS and technical documentation for IVD classes A sterile, B, C & D and for MD Classes I (sterile, measuring or reusable surgical instrument), IIa, IIb and III. The NB issues a CE marking certificate for the assessed devices and surveillance audits will take place to maintain the CE certificate to ensure ongoing compliance with MDR/IVDR (IVDR, 2017 and MDR, 2017). Next, the preparation of the declaration of conformity (DoC), affixing of the CE marking. Registration of the device and Unique Device Identified (UDI) in the EUDAMED database (voluntary for the time being). UDI must be on the label and associated regulatory documents. Finally, after the legal manufacturer starts placing their device on the market, starts the post-market phase in which the Clinical Evaluation Report/ Performance Evaluation Report, technical documentation, QMS and Post-market surveillance (PMS) activities must be kept updated. For devices where there is Notify Body involvement, the NB shall be audited each year to ensure ongoing compliance with IVDR/MDR. Failure to pass the audit will invalidate the CE Marking certificate which blocks commercialization of devices in the EU union.

The ***Table 8*** to **Table 17** and **Figure 2** represent the parallel comparison of the content of both regulations. The different chapters specific to MDR or IVDR are marked in bold text.

Table 5: *MDR and IVDR Regulations comparison on Scope and Definitions*

MDR CHAPTER I SCOPE AND DEFINITIONS	**IVDR CHAPTER I INTRODUCTORY PROVISIONS**
Article 1: subject Matter and Scope Article 2: Definitions Article 3: **Amendment of certain definitions** Article 4: Regulatory status of products	Article 1: subject Matter and Scope Article 2: Definitions Article 3: Regulatory status of products Article 4: **Genetic information, counselling and informed consent**

Table 6 indicates the new definitions of medical device and in vitro diagnostic medical device. The new definitions are more extended and a device to be place into EU market needs to be analyzed whether it falls into the scope and definition of IVDR and MDR.

Table 6: *Medical Devices and in vitro diagnostic medical devices. Each device needs to be qualified whether it falls into the scope of IVDR or MDR article 2.*

MDR Article 2 (1)	IVDR Article 2(2)
'**medical device'** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: — devices for the control or support of conception; — products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point	**'in vitro diagnostic medical device'** means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) concerning the predisposition to a medical condition or a disease; (d) to determine the safety and compatibility with potential recipients; (e) to predict treatment response or reactions; (f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices;

Table 7: *MDR and IVDR Regulations comparison on Making available and putting into service available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement*

MDR CHAPTER II MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT	IVDR CHAPTER II MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT
Article 5: Placing on the market and putting into service	Article 5: Placing on the market and putting into service
Article 6: Distance sales	Article 6: Distance sales
Article 7 Claims	Article 7 Claims
Article 8 Use of harmonised standards	Article 8 Use of harmonised standards
Article 9 Common specifications	Article 9 Common specifications
Article 10 General obligations of manufacturers	Article 10 General obligations of manufacturers
Article 11 Authorised representative	Article 11 Authorised representative
Article 12 Change of authorised representative	Article 12 Change of authorised representative
Article 13 General obligations of importers	Article 13 General obligations of importers
Article 14 General obligations of distributors	Article 14 General obligations of distributors
Article 15 Person responsible for regulatory compliance	Article 15 Person responsible for regulatory compliance
Article 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons	Article 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons
Article 17 Single-use devices and their reprocessing	Article 17 EU declaration of conformity
Article 18 Implant card and information to be supplied to the patient with an implanted device	Article 18 CE marking of conformity
Article 19 EU declaration of conformity	Article 19 Devices for special purposes
Article 20 CE marking of conformity	Article 20 Parts and components
Article 21 Devices for special purposes	Article 21 Free movement
Article 22 Systems and procedure packs	
Article 23 Parts and components	
Article 24 Free movement	

Table 8: *Comparison between definitions related to placing on the market, making available and putting into service.*

Placing on the market	making available on the market	putting into service
MDR 2017/745 – Art.2(28) 'placing on the market' means the first making available of a device, other than an ***investigational device***, on the Union Market. **IVDR 2017/746 Art. 2(21)** placing on the market' means the first making available of a device, other than a device for ***performance study***, on the Union market;	**MDR 2017/745 - Art. 2(27)** 'making available on the market' means any supply of a device, other than an ***investigational device***, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. **IVDR 2017/746 Art. 2(20)** making available on the market' means any supply of a device, other than a de-	**MDR 2017/745 Art. 2(29)** 'putting into service' means the stage at which a device, other than an ***investigational device***, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose. **IVDR 2017/746 Art.2(22)** putting into service' means the stage at which a device, other than a device for ***performance study***, has been made

	vice for ***performance study***, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	available to the final user as being ready for use on the Union market for the first time for its intended purpose

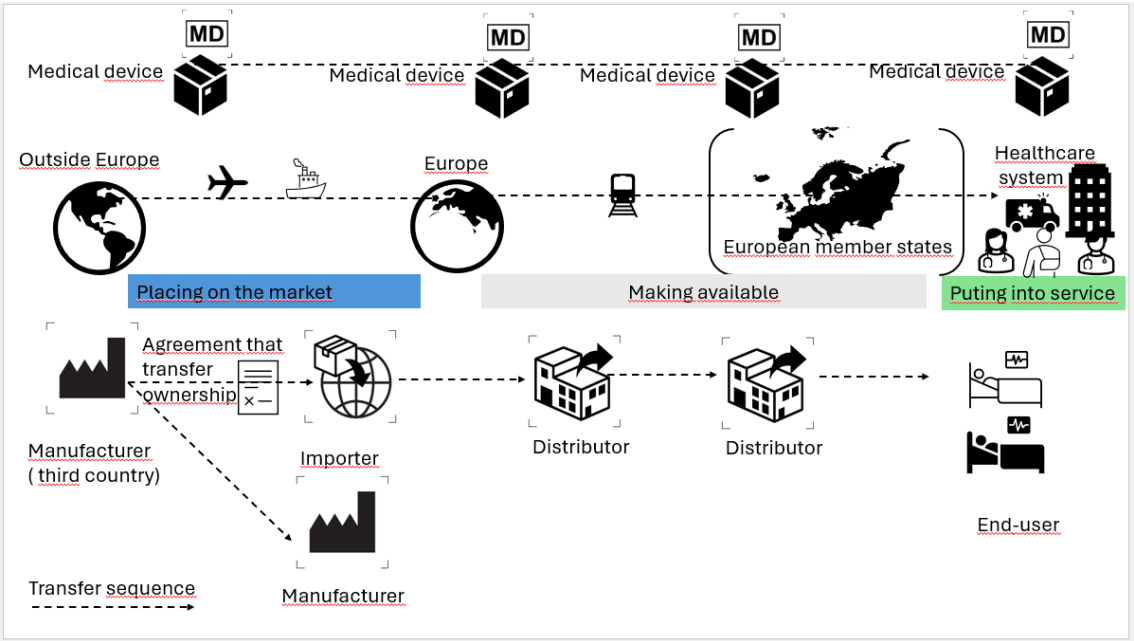

Figure 2: Manufacturers (in the European union) and importer (if the manufacturer is outside EU) are the economic operators involved when the products are place on the market. The products are placed on the market when the ownership is transferred to another entity (distributor or provider). These entities could belong to the manufacturer as part of their supply chain. The latter entity (distributor) that has ownership can sell the product to another entity or end-user, this is referred to as making available on the market. When the products reach the end-user and the user utilizes according to intended use, this is referred to putting into service. Remarks about placing on the market: This is done by manufacturer or an importer. This takes place when the products are provided to the distributor or end-user for the first time. This takes place for each individual product. This requires an agreement or equivalent to transfer ownership. Placing on the market is NOT when the consumer in a third country buys the product and brings it into EU, neither when the product is transferred from the manufacturer in a third country to an authorized representative in EU. Neither when the product is in transit from a third country in EU customs territory, nor when the product is in stock or

warehouse of the manufacturer (or authorized representative) or has been transferred to a manufacturer for further measures (for example assembling, packaging, processing, sterilization, labeling) (IVDR/MDR, 2017; RAPS, 2022, *Prepared by Pérez-Gamarra, 2025)*

Table 9: *MDR and IVDR Regulations comparison on Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices*

MDR CHAPTER III IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES	**IVDR CHAPTER III IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES**
Article 25 Identification within the supply chain	Article 22 Identification within the supply chain
Article 26 Medical devices nomenclature	Article 23 Medical devices nomenclature
Article 27 Unique Device Identification system	Article 24 Unique Device Identification system
Article 28 UDI database	Article 25 UDI database
Article 29 Registration of devices	Article 26 Registration of devices
Article 30 Electronic system for registration of economic operators	Article 27 Electronic system for registration of economic operators
Article 31 Registration of manufacturers, authorised representatives and importers	Article 28 Registration of manufacturers, authorised representatives and importers
Article 32 Summary of safety and clinical performance	Article 29 Summary of safety and performance
Article 33 European database on medical devices	Article 30 European database on medical devices
Article 34 Functionality of Eudamed	

Table 10: *MDR and IVDR Regulations comparison on Notify Bodies*

MDR CHAPTER IV NOTIFIED BODIES	**IVDR CHAPTER IV NOTIFIED BODIES**
Article 35 Authorities responsible for notified bodies	Article 31 Authorities responsible for notified bodies
Article 36 Requirements relating to notified bodies	Article 32 Requirements relating to notified bodies
Article 37 Subsidiaries and subcontracting	Article 33 Subsidiaries and subcontracting
Article 38 Application by conformity assessment bodies for designation	Article 34 Application by conformity assessment bodies for designation
Article 39 Assessment of the application	Article 35 Assessment of the application
Article 40 Nomination of experts for joint assessment of applications for notification	Article 36 Nomination of experts for joint assessment of applications for notification
Article 41 Language requirements	Article 37 Language requirements
Article 42 Designation and notification procedure	Article 38 Designation and notification procedure
Article 43 Identification number and list of notified bodies	Article 39 Identification number and list of notified bodies

Article 44 Monitoring and re-assessment of notified bodies	Article 40 Monitoring and re-assessment of notified bodies
Article 45 Review of notified body assessment of technical documentation and clinical evaluation	Article 41 Review of notified body assessment of technical documentation and performance evaluation
Documentation	Documentation
Article 46 Changes to designations and notifications	Article 42 Changes to designations and notifications
Article 47 Challenge to the competence of notified bodies	Article 43 Challenge to the competence of notified bodies
Article 48 Peer review and exchange of experience between authorities responsible for notified bodies	Article 44 Peer review and exchange of experience between authorities responsible for notified bodies
Article 49 Coordination of notified bodies	Article 45 Coordination of notified bodies
Article 50 List of standard fees	Article 46 List of standard fees

Table 11: *MDR and IVDR Regulations comparison on classification and conformity assessment*

MDR CHAPTER V CLASSIFICATION AND CONFORMITY ASSESSMENT	**IVDR CHAPTER V CLASSIFICATION AND CONFORMITY ASSESSMENT**
Article 51 Classification of devices	Article 47 Classification of devices
Article 52 Conformity assessment procedures	Article 48 Conformity assessment procedures
Article 53 Involvement of notified bodies in conformity assessment procedures	Article 49 Involvement of notified bodies in conformity assessment procedures
Article 54 Clinical evaluation consultation procedure for certain class III and class IIb devices	**Article 50 Mechanism for scrutiny of conformity assessments of class D devices**
Article 55 Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices	Article 51 Certificates of conformity
Article 56 Certificates of conformity	Article 52 Electronic system on notified bodies and on certificates of conformity
Article 57 Electronic system on notified bodies and on certificates of conformity	Article 53 Voluntary change of notified body
Article 58 Voluntary change of notified body	Article 54 Derogation from the conformity assessment procedures
Article 59 Derogation from the conformity assessment procedures	Article 55 Certificate of free sale
Article 60 Certificate of free sale	

Table 12: *Parallel Analysis Of MDR Clinical Evaluation and Clinical Investigations versus IVDR Clinical Evidence, Performance Evaluation And Performance Studies*

MDR CHAPTER VI CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS	**IVDR CHAPTER VI CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES**
Article 61 Clinical evaluation	Article 56 Performance evaluation and clinical evidence

Article 62 General requirements regarding clinical investigations conducted to demonstrate conformity of Devices	Article 57 General requirements regarding performance studies
Article 63 Informed consent	Article 58 Additional requirements for certain performance studies
Article 64 Clinical investigations on incapacitated subjects	Article 59 Informed consent
Article 65 Clinical investigations on minors	Article 60 Performance studies on incapacitated subjects
Article 66 Clinical investigations on pregnant or breast-feeding women	Article 61 Performance studies on minors
Article 67 Additional national measures	Article 62 Performance studies on pregnant or breast-feeding women
Article 68 Clinical investigations in emergency situations	Article 63 Additional national measures
Article 69 Damage compensation	Article 64 Performance studies in emergency situations
Article 70 Application for clinical investigations	Article 65 Damage compensation
Article 71 Assessment by Member States	Article 66 Application for performance studies
Article 72 Conduct of a clinical investigation	Article 67 Assessment by Member States
Article 73 Electronic system on clinical investigations	Article 68 Conduct of a performance study
Article 74 Clinical investigations regarding devices bearing the CE marking	Article 69 Electronic system on performance studies
Article 75 Substantial modifications to clinical investigations	Article 70 Performance studies regarding devices bearing the CE marking
Article 76 Corrective measures to be taken by Member States and information exchange between Member States	Article 71 Substantial modifications to performance studies
Article 77 Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination	Article 72 Corrective measures to be taken by Member States and information exchange between Member States on performance studies
Article 78 Coordinated assessment procedure for clinical investigations	Article 73 Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination
Article 79 Review of coordinated assessment procedure	Article 74 Coordinated assessment procedure for performance studies
Article 80 Recording and reporting of adverse events that occur during clinical investigations	Article 75 Review of the coordinated assessment procedure
Article 81 Implementing acts	Article 76 Recording and reporting of adverse events that occur during performance studies
Article 82 Requirements regarding other clinical investigations	Article 77 Implementing acts

Table 13: *MDR and IVDR Regulations Comparison On Post-Market Surveillance, Vigilance and Market Surveillance*

MDR CHAPTER VII POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE	**IVDR CHAPTER VII POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE**
Post-market surveillance	*Post-market surveillance*
Article 83 Post-market surveillance system of the manufacture	Article 78 Post-market surveillance system of the manufacturer
Article 84 Post-market surveillance plan	Article 79 Post-market surveillance plan
Article 85 Post-market surveillance report	Article 80 Post-market surveillance report
Article 86 Periodic safety update report	Article 81 Periodic safety update report

Vigilance	*Vigilance*
Article 87 Reporting of serious incidents and field safety corrective actions	Article 82 Reporting of serious incidents and field safety corrective actions
Article 88 Trend reporting	Article 83 Trend reporting
Article 89 Analysis of serious incidents and field safety corrective actions	Article 84 Analysis of serious incidents and field safety corrective actions
Article 90 Analysis of vigilance data	Article 85 Analysis of vigilance data
Article 91 Implementing acts	Article 86 Implementing acts
Article 92 Electronic system on vigilance and on post-market surveillance	Article 87 Electronic system on vigilance and post-market surveillance
Market Surveillance	*Market Surveillance*
Article 93 Market surveillance activities	Article 88 Market surveillance activities
Article 94 Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance	Article 89 Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance
Article 95 Procedure for dealing with devices presenting an unacceptable risk to health and safety	Article 90 Procedure for dealing with devices presenting an unacceptable risk to health and safety
Article 96 Procedure for evaluating national measures at Union level	Article 91 Procedure for evaluating national measures at Union level
Article 97 Other non-compliance	Article 92 Other non-compliance
Article 98 Preventive health protection measures	Article 93 Preventive health protection measures
Article 99 Good administrative practice	Article 94 Good administrative practice
Article 100 Electronic system on market surveillance	Article 95 Electronic system on market surveillance

Table 14: *MDR and IVDR regulations comparison on cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers*

MDR CHAPTER VIII COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS	**IVDR CHAPTER VIII COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EU REFERENCE LABORATORIES AND DEVICE REGISTERS**
Article 101 Competent authorities	Article 96 Competent authorities
Article 102 Cooperation	Article 97 Cooperation
Article 103 Medical Device Coordination Group	Article 98 Medical Device Coordination Group
Article 104 Support by the Commission	Article 99 Tasks of the MDCG
Article 105 Tasks of the MDCG	Article 100 The European Union reference laboratories
Article 106 Provision of scientific, technical and clinical opinions and advice	Article 101 Device registers and databanks
Article 107 Conflict of interests	
Article 108 Device registers and databanks	

Table 15: MDR and IVDR regulations comparison on confidentiality, data protection, funding and penalties

MDR CHAPTER IX CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES	IVDR CHAPTER IX CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES
Article 109 Confidentiality	Article 102 Confidentiality
Article 110 Data protection	Article 103 Data protection
Article 111 Levying of fees	Article 104 Levying of fees
Article 112 Funding of activities related to designation and monitoring of notified bodies	Article 105 Funding of activities related to designation and monitoring of notified bodies
Article 113 Penalties	Article 106 Penalties

Table 16: MDR and IVDR regulations comparison on Final Provisions

MDR CHAPTER X FINAL PROVISIONS	IVDR CHAPTER X FINAL PROVISIONS
Article 114 Committee procedure	Article 107 Committee procedure
Article 115 Exercise of the delegation	Article 108 Exercise of the delegation
Article 116 Separate delegated acts for different delegated powers	Article 109 Separate delegated acts for different delegated powers
Article 117 Amendment to Directive 2001/83/EC	Article 110 Transitional provisions
Article 118 Amendment to Regulation (EC) No 178/2002	Article 111 Evaluation
Article 119 Amendment to Regulation (EC) No 1223/2009	Article 112 Repeal
Article 120 Transitional provisions	Article 113 Entry into force and date of application
Article 121 Evaluation	
Article 122 Repeal	
Article 123 Entry into force and date of application	

Table 17: MDR and IVDR regulations comparison on Annexes

MDR ANNEXES	IVDR ANNEXES
I General safety and performance requirements	I General safety and performance requirements
II Technical documentation	II Technical documentation
III Technical documentation on post-market surveillance	III Technical documentation on post-market surveillance
IV EU declaration of conformity	IV EU declaration of conformity
V CE marking of conformity	V CE marking of conformity
VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29;and the UDI system	VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 26(3) and 28, core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 25 and 26 and the UDI system
VII Requirements to be met by notified bodies	VII Requirements to be met by notified bodies

VIII Classification rules	VIII Classification rules
IX Conformity assessment based on a quality management system and assessment of the technical documentation	IX Conformity assessment based on a quality management system and on assessment of technical documentation
X Conformity assessment based on type examination	X Conformity assessment based on type examination
XI Conformity assessment based on product conformity verification	XI Conformity assessment based on production quality assurance
XII Certificates issued by a notified body	XII Certificates issued by a notified body
XIII Procedure for custom-made devices	XIII Performance evaluation, performance studies and post-market performance follow-up
XIV Clinical evaluation and post-market clinical follow-up	XIV Interventional clinical performance studies and certain other performance studies
XV Clinical investigations	XV Correlation table
XVI List of groups of products without an intended medical purpose referred to in Article 1(2)	
XVII Correlation table	

2.5.2 Regulation EU 2023/607 and Regulation EU 2024/1860 transitional provisions for certain medical devices and in vitro diagnostic medical devices- Amendments to Regulations (EU) 2017/745 and (EU) 2017/746

The EU commission released further regulations to protect the EU market from shortage and share information in case of interruption/discontinuation of supply of IVD/MD that can negatively affect member state(s) of EU, as well as permit a smooth transition to IVDR and MDR (EU 2023/607 and EU 2024/1860, See table X and Y). **Regulation 2023/607** (***Table 18***) amends the existing regulations MDR (EU 2017/745) and IVDR (2017/746) addressing the risk of shortage of medical devices in EU due to the slower than anticipated transition to implement IVDR and MDR. The key points of 2023/607 include: i) Extended transition timelines to prevent shortage of IVD and MD devices in EU market. ii) Legacy devices that are CE marked under the directives (MDD/AIMDD) can remain “legacy devices” under certain conditions that include no significant change to design nor intended purpose and ensuring devices do not present an unacceptable risk to health or safety. Iii) QMS in place per Article 10(9) by 26 May 2024 and iv) Manufactures must ensure appropriate surveillance of legacy devices to benefit from extended timelines and confirmation letters issued by Notified Body that the device qualifies for the extended transition timelines. **Regulation 2024/1860** (*Table 19***)** amends the existing regulations MDR (EU 2017/745) and IVDR (2017/746) focusing on

smoother transition and better management of MD and IVDs in EU. The key points are i) Gradual roll-out of European Database on Medical Devices (EUDAMED). This gradual roll-out aims to ensure that all necessary modules are published, confirmed and communicated effectively ii) Obligation to inform in case of interruption or discontinuation of supply. The manufacturer shall inform the Competent Authority in the member state of their NB at least six months in advance if they anticipate any interruption or discontinuation of the supply of certain devices. This mandatory notification is mandatory if the supply disruption could reasonably result in serious harm or risk of serious harm in one or more member states. Iii)QMS requirements, registration and market authorization timelines for IVDs.

Table 18: *Extension timelines for MDR (Regulation 2023/607)*

26 May 2024	**26 September 2024**	**26 May 2026**	**31 December 2027**	**31 December 2028**
Manufacturers have implemented an MDR compliant QMS and have formally applied to a Notified Body	The Notified Body and the manufacturer have signed a formal written agreement.	Class III custom-made implantable legacy devices to be MDR certified	Class III and IIb implantable legacy devices (excluding WET) to be MDR certified	Other Class IIb, Class IIa, Class Is and Class Im legacy devices to be MDR certified Legacy devices up-classified under the MDR and now requiring Notified Body involvement, to be MDR certified[1] All legacy devices must comply with the MDR[2]

1 Only for legacy devices whose Declaration of Conformity (DoC) was signed by 26 May 2021 (e.g., Class Ir).

2 The sell-off period has been removed. Legacy devices placed on the market before the end of the transition period can be made further available on the market without legal time restrictions.

Table 19: Extension timelines for IVDR (Regulation 2024/1860)

Class IVD	**QMS complaint with IVDR**	**Formal application lodged with NB**	**Formal written agreement with a NB signed**	**Transition deadline**
IVDD Certified devices1	26 May 2025	26 May 2025	26 September 2025	31 September 2027
Class D Self declared2				
Class C Self declared 2		26 May 2026	26 September 2026	31 September 2028
Class B and A2 Self declared		26 May 2027	26 September 2027	31 September 2029

1 IVDD certified devices: IVDD Certification from a Notified Body.

2 IVDD self-declared devices: IVDs on the market under IVDD that did not need a Notified Body Certification.

The sell-off period for self-certified IVDs already placed on the market under the IVDD has been removed. These devices can be made available on the market without legal time restrictions. For in-house devices, the requirement to justify that an equivalent device is not available on the market is postponed until May 2028.

2.6 Key Documentation aspects of IVDR and/or MDR

Both IVDR (EU 2017/746) and MDR (EU 2017/745) are prescriptive on the requirements that manufacturers should comply with and what documents notified bodies shall review and emit as well as what documents economic operators shall verify (See graphic representation in Figure 3: Key Aspect of documentation related to IVDR and . Technical documentation (TD, details of requirements in Annex II of IVDR and MDR) and the technical documentation post-market surveillance (details of requirements in Annex III of IVDR and MDR) provide objective evidence that requirements described throughout the regulations are fulfilled and the product is safe, effective and meets its intended use. The technical documentation shall be prepared taking into consideration the type of device and the risk class. The TD captures details on the medical device or *in vitro diagnostic* medical device related to device description, information supplied with the device, design and manufacturer information, General Safety and Performance requirements, risk management, design verification and validation and post-market surveillance. Once the manufacturer fulfilled the requirements deemed appropriate to IVDR- or MDR- regulation, the organization is able to proceed with the conformity

assessment (self-certified or with a notified body) and affix the *Conformité Européenne mark (also, known as CE mark)*. The CE mark is a symbol that can be affixed to a product to indicate that this complies with EU legislation and enables free movement, The CE marking and other mandatory markings can be affixed according to Annex V of MDR or IVDR. The EU guidance document 2022/C 247/01 provides further descriptions on how to implement legislation and EU product rules. The CE marking represents that product conforms to EU regulations and applicable standards, representing product safety and consumer protection. CE mark has consistent proportions, and this mark must be carefully prepared. Unfortunately, there is a misleading abbreviation “CE” that stands for China Export which is not linked to EU regulation, and it is not a valid mark recognize by EU, the China Export mark does not meet dimensions and proportions given in EU legislation (Weerth, 2019). After the conformity assessment is completed by the Notified Body (applicable for all MD/IVD classes, except for MD class I and IVD class A), the NB emits a certificate of conformity (IVDR Art.51 and MDR Art. 56) which is valid for 5 years.

IVDR and MDR support international export activities, whenever the manufacturer or its Authorised Representative registered in an EU member state can request the competent authority of the Member state where they registered place of business to issue the Certificate of Free Sale (IVDR article 55 and MDR article 60). The Free sale certificate facilitates trade is a certificate recognized by other regulatory bodies that the device already meets EU safety and performance standards enabling market access to a wide range of non-EU countries.

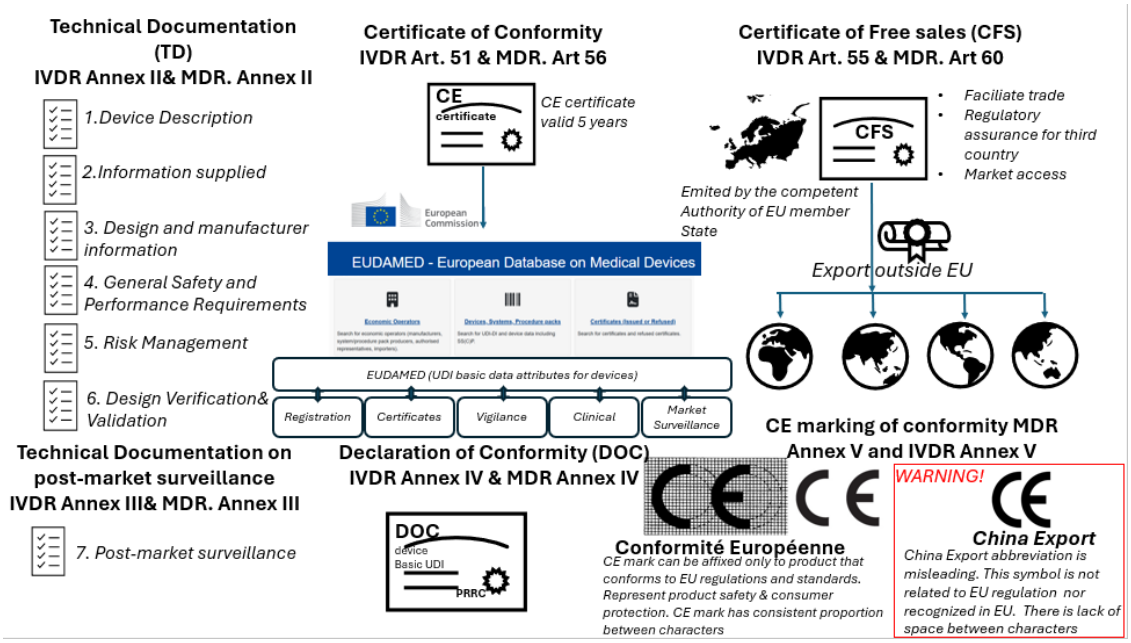

Figure 3: Key Aspect of documentation related to IVDR and MDR. (*Prepared by Pérez-Gamarra, 2025*

2.7 The impact of the Regulatory Landscape

Implementing new regulations has a different impact. For instance, Guerra-Bretaña & Flórez-Rendón (2018) reviewed the impact of regulations on innovation in medical devices and concludes that regulations exist to protect patients from products that are not safe and promote public health by introducing safe innovations to the market. These authors discussed that exist the risk of ´placing into the market´ that do not have exhausting tested devices and highlighted that researchers, manufacturers and physicians do have responsibility related to ensure and/or verify safety and effectiveness of devices. This study also highlights that there is need for a collaborative regulatory research and device evaluation to improve regulatory pathways for emerging and pioneering technologies.

Maci and Maresova (2022) make a systematic review on the economic assessment of regulations and highlight that the most common factors on how to measure the impact are cost-effectiveness analysis, internal rate of return, budget impact analysis, whereas non-economic indicators include time-to-market. Being

the cost related indicators, the most common used factor to measure effectiveness of regulations from different stakeholders' perspective (researchers, regulators, manufacturers, healthcare providers).

2.8 Monitoring the Availability of IVD and MD in Europe

The study commissioned by the European Commission via the European Health and Digital Executive Agency (HADEA) (2022-2025) aims at monitoring and analyse the availability of medical devices on the EU market in the context of the implementation of Regulations (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The Data is continuously updated and the dashboards (Austrian National Public Health Institute, Arete, Civic Consulting, 2024).

The current monitoring of availability of MD in Europe are captured by the EU commission continuously in Figure 4 to Figure 10. (Austrian National Public Health Institute, Arete, Civic Consulting, 2024). The take home message from the monitoring of MD indicates that there are availability problems reported, being class III the risk class of CE-marked device. Also, there might not be available alternative treatments or medical procedures available for reported types of devices. The timelines to issue a QMS certificate can take up to 24 months in the worst-case scenario and in average 13-18 months. The timelines to issue a QMS and product certificate can take up to 24 months in the worst-case scenario and in average 13-18 months. The signature of a written agreement can take on average 1-2 months and in the worst-case scenario more than 6 months. The highest reason for application refusal (54% of cases) is because the application is outside scope of notified body´s designation. Also, there are 224 QMS certified manufacturers for their full portfolio, 273 companies with a written agreement with NB.175 manufacturers have transferred products/technical documentations to the MDR. Furthermore, *"242 manufacturers had 100% of the MD already transitioned or planned to transition to MDR.* Estimate direct average cost per already issued certificate for QMS initial QMS (58346 euros) and 85119 euros for total initial cost product. The most frequent reason for not having fully transitioned all MD to MDR yet is due to i) product revenue too low to transition ii) MD to be replaced with updated/more innovative product iii) too long certification time iv)

lack of clinical evidence and v) MD to be discontinued. Next, it is estimated that for the end of the transition period in 2028: 111746 MD class IIa are certified for MDR and there are 2391 certificates based on Annex IX(I+III)" (Austrian National Public Health Institute, Arete, Civic Consulting, 2024). In addition, 161 manufacturers have stopped or planned to stop marketing or supply of devices to the EU since 2021. Among the most frequent reasons to stop or planning to stop production/marketing/supply of MD to EU market is due to revenue not justifying reapproval, products with low sales volumes, products with low profitability, products to be replaced/updated. Finally, Manufacturers located outside Europe had cancelled agreements with their Authorized representative (AR). 9 of them AR clients have stopped production/marketing/supply in the Eu market. (Austrian National Public Health Institute, Arete, Civic Consulting, 2024)

The current monitoring of availability of IVD in Europe are captured by the EU commission continuously in Figure 11 to Figure 17 (Austrian National Public Health Institute, Arete, Civic Consulting, 2024). The take home message from the monitoring of IVD indicates that there are few problems with IVD availability had been reported. Also, the time needed to issue a QMS certificate only can range between 6-18 months and in the worst-case scenario up to 24 months. Whereas the average to issue a QMS and product certificate under IVDR takes 13-18 months and in the worst-case scenario up to 24 months. In addition, 44 manufacturers have QMS certified for their full portfolio. 47 manufacturers have all devices covered. 38 IVD manufacturers have transferred their first product/technical documentation to IVDR. Furthermore, 45 manufacturers have 90-100% of IVDs already transitioned or planned to transition to IVDR whereas 31 IVD manufacturers are planning to transfer or had transferred less than 10% of IVDs. Also, the estimate direct average cost per already issued certificate is 54626 eur for total initial cost QMS and 55051eur for total initial cost product. In addition, the most frequent reasons for not having fully transitioned to IVDR is due to i) product revenue too low to transition ii) too long certificate time iii) IVD to be replaced with updated/innovative product. Next, 90 IVD manufacturers estimate that less than 10% of product portfolio foreseen for transition already having IVDR certification. There are expectations of 2203 new devices for which applications will be sub-

mitted till the beginning of 2025. In the future, it is estimated that 5744 IVDR devices of class B will be placed on the market at the end of the transitional period in 2027. Finally, 27 manufacturers of IVDs stopped or planned to stop production, marketing or supply of devices to the EU since 2021. The most frequent reasons for IVD manufacturers having stopped or planning to stop production, marketing or supply of devices to the EU market are i) revenue not justifying reapproval ii) products with low sales volume iii) products with low profitability iv) devices will be replaced by updated/new products v) products at the end of their lifecycle.

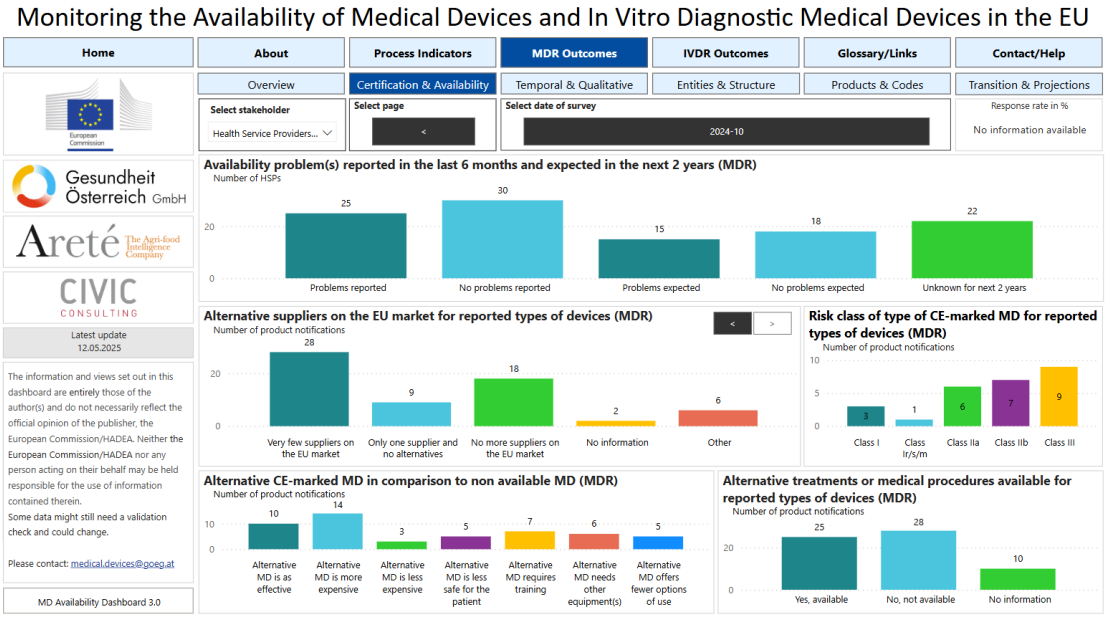

Figure 4: *MDR Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 5)*

Highlight of Figure 4, there are availability problems reported, class III the risk class of CE-marked device. Also, there might not be available alternative treatments or medical procedures available for reported types of devices.

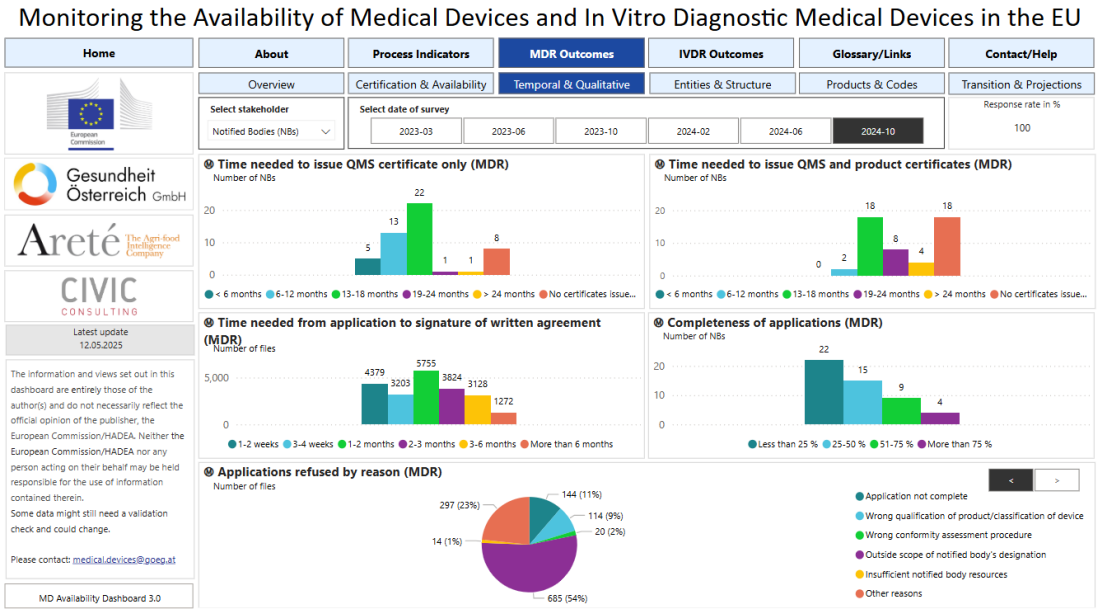

Figure 5: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 6)*

Highlight of Figure 5: The timelines to issue a QMS certificate can take up more or less 24 months in the worst-case scenario and in average 13-18 months. The timelines to issue a QMS and product certificate can take up to 24 months in the worst-case scenario and on average 13-18 months. The signature of a written agreement can take on average 1-2 months and in the worst-case scenario more than 6 months. The highest reason for application refusal (54% of cases) is because the application is outside scope of notified body´s designation.

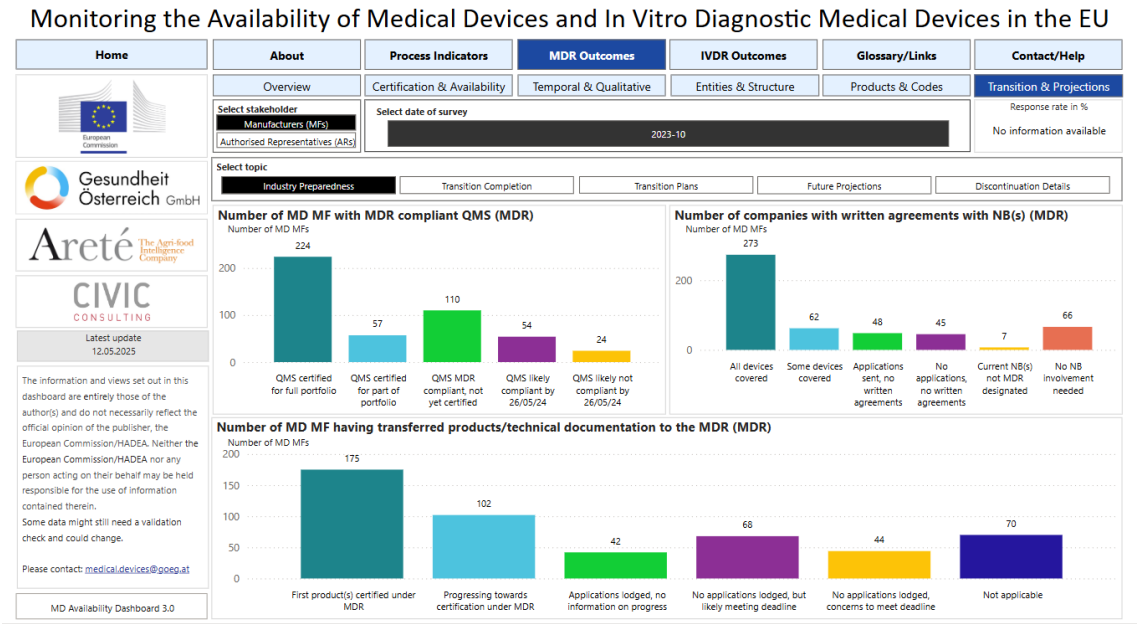

Figure 6: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 10)*

Highlight of Figure 6, there are 224 QMS certified manufacturers for their full portfolio, 273 companies with a written agreement with NB.175 manufacturers have transferred products/technical documentations to the MDR.

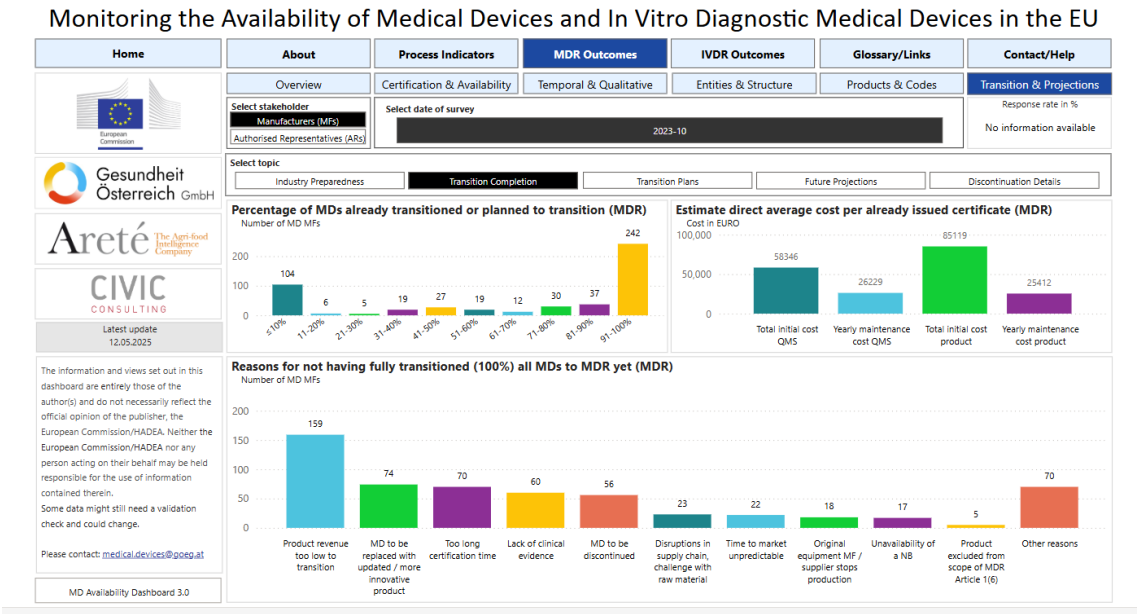

Figure 7: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 11)*

Highlight of Figure 7; 242 manufacturers had 100% of the MD already transitioned or planned to transition to MDR. Estimate direct average cost per already issued certificate for QMS initial QMS (58346 euros) and 85119 euros for total initial cost product. The most frequent reason for not having fully transitioned all MD to MDR yet is due to i) product revenue too low to transition ii)MD to be replaced with updated/more innovative product iii) too long certification time iv) lack of clinical evidence and v) MD to be discontinued.

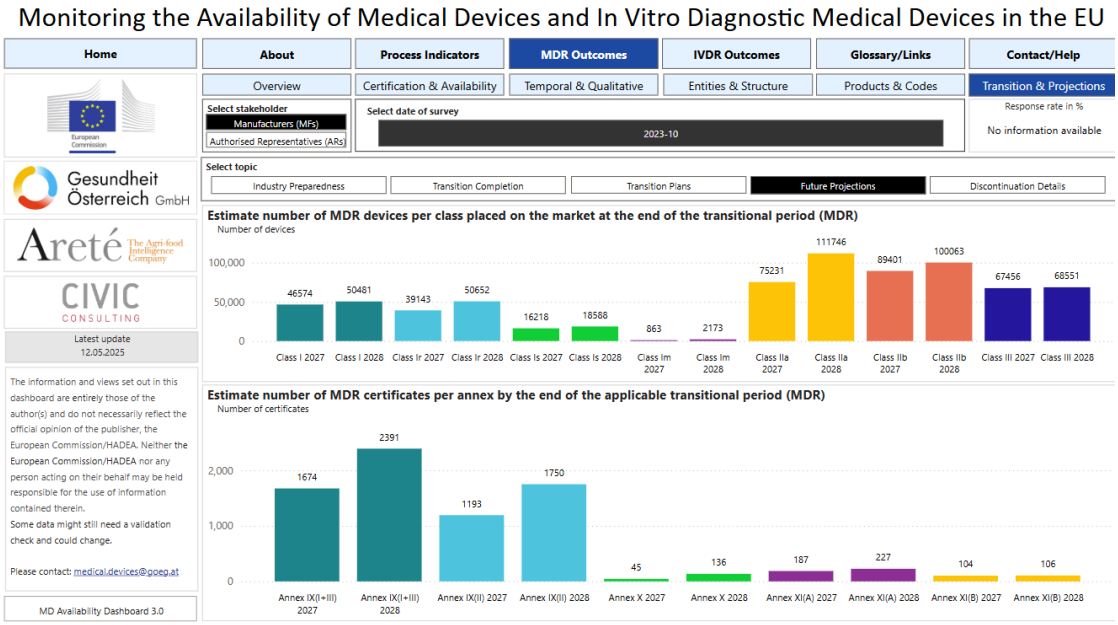

Figure 8: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 13)*

Highlight of Figure 8, it is estimated that for the end of the transition period in 2028: 111746 MD class IIa are certified for MDR and there are 2391 certificates based on Annex IX(I+III)

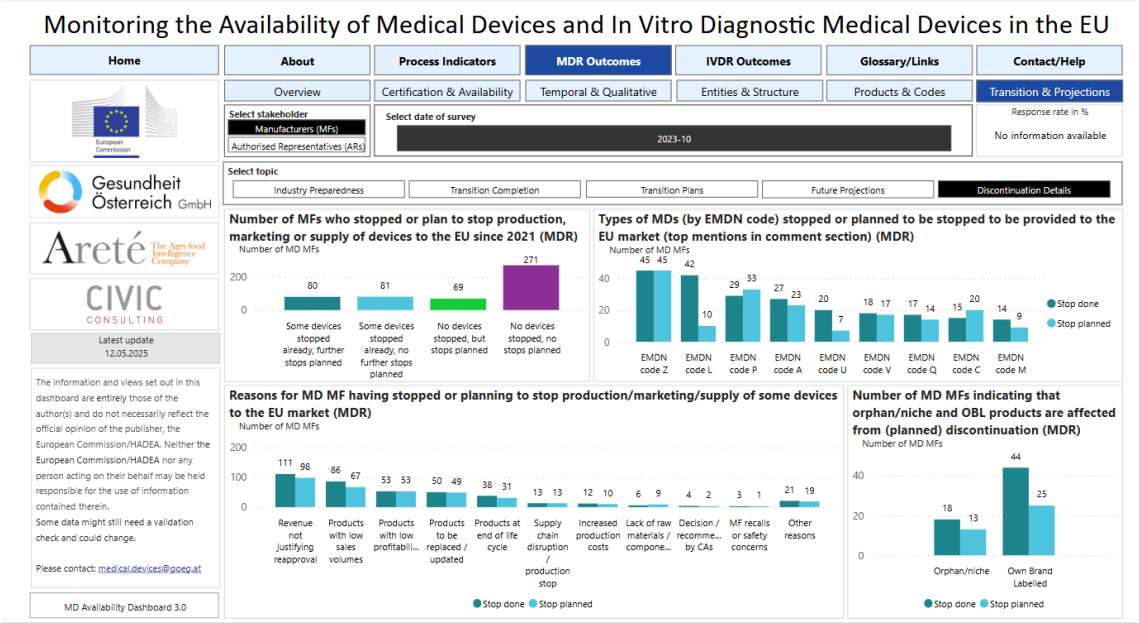

Figure 9: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 14)*

Highlight of Figure 9; 161 manufacturers have stop or planned to stop marketing or supply of devices to the EU since 2021. Among the most frequent reasons to stop or planning to stop production/marketing/supply of MD to EU market is due to revenue not justifying reapproval, products with low sales volumes, products with low profitability, products to be replaced/updated.

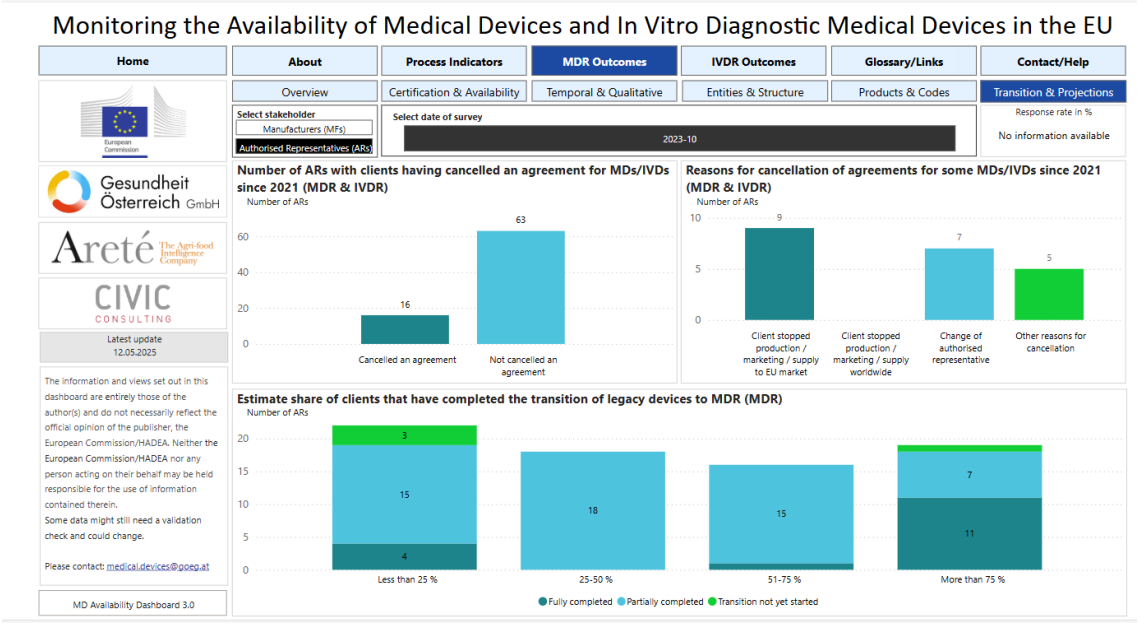

Figure 10: MDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 15)*

Highlight: of Figure 10; 16 Manufacturers located outside Europe had cancelled agreements with their Authorized representative (AR). 9 of their AR clients have stopped production/marketing/supply in the Eu market.

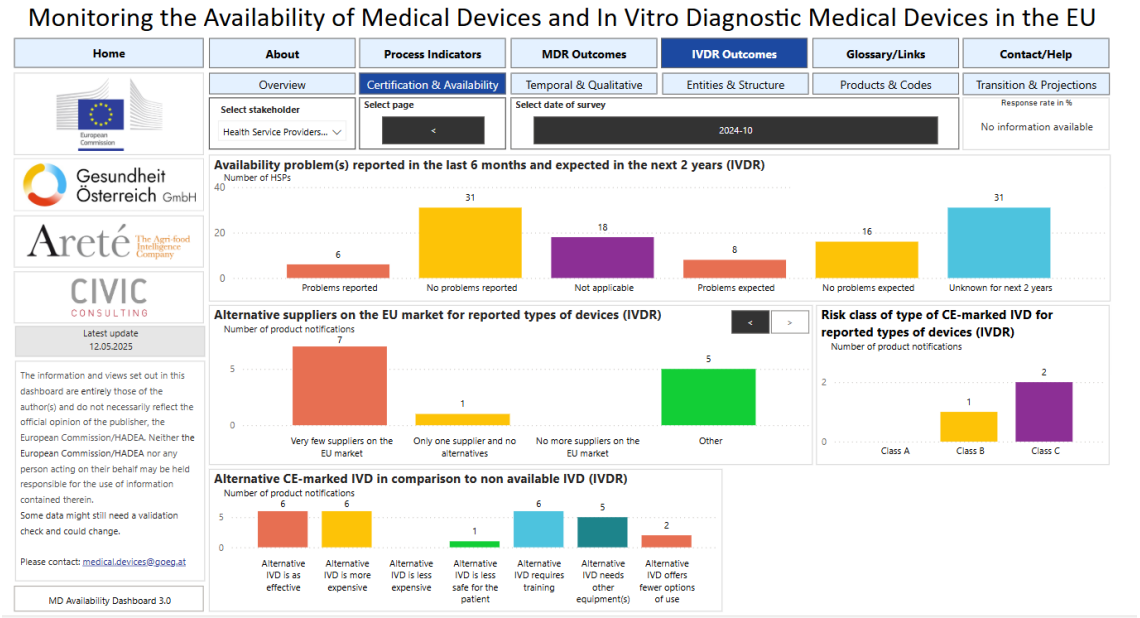

Figure 11: IVDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 17)*

Highlight of Figure 11: Few problems with IVD availability have been reported.

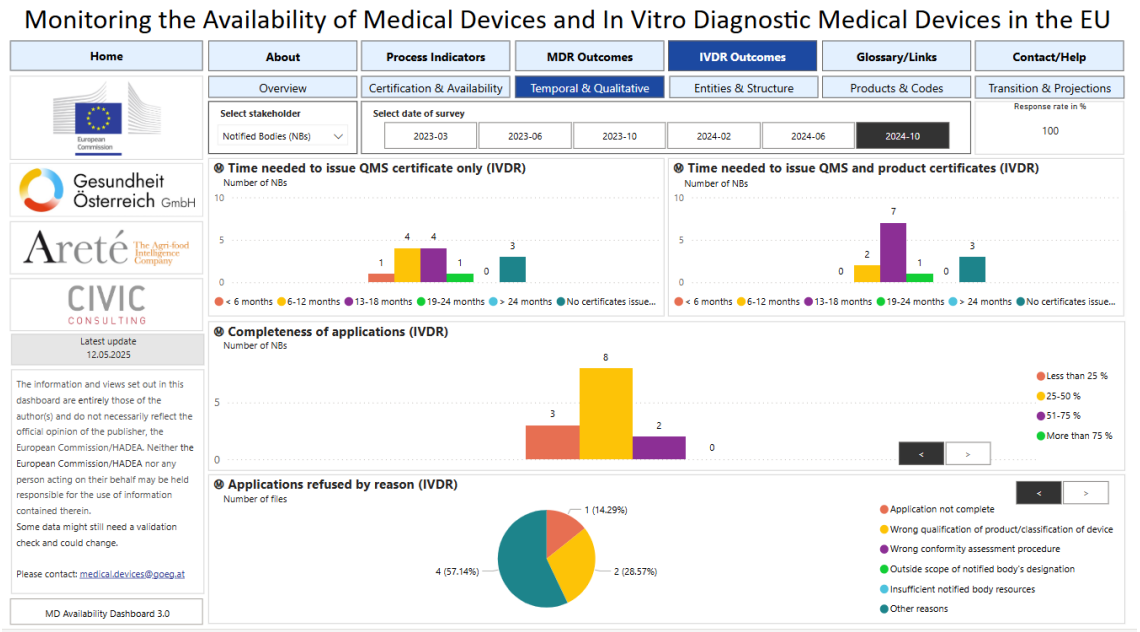

Figure 12: IVDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 18)*

Highlight of Figure 12, the time needed to issue a QMS certificate only can range between 6-18 months and in the worst-case scenario up to 24 months. Whereas the average to issue a QMS and product certificate under IVDR takes 13-18 months and in the worst-case scenario up to 24 months.

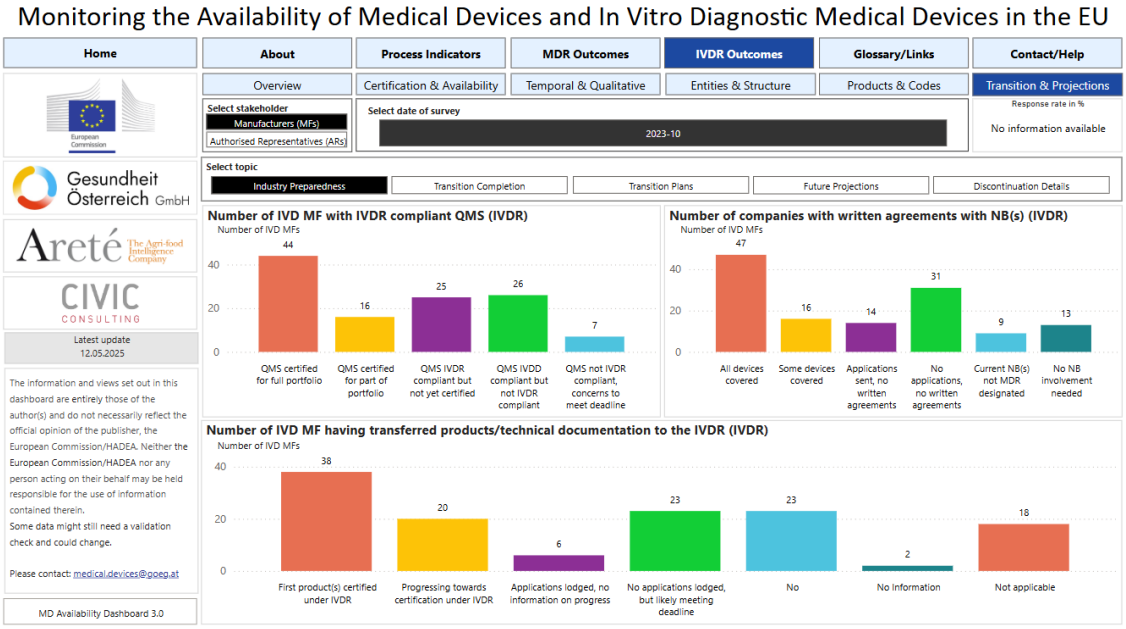

Figure 13: IVDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 21)*

Highlight of Figure 13; 44 manufacturers have QMS certified for their full portfolio. 47 manufacturers have all devices covered. 38 IVD manufacturers have transferred their first product/technical documentation to IVDR.

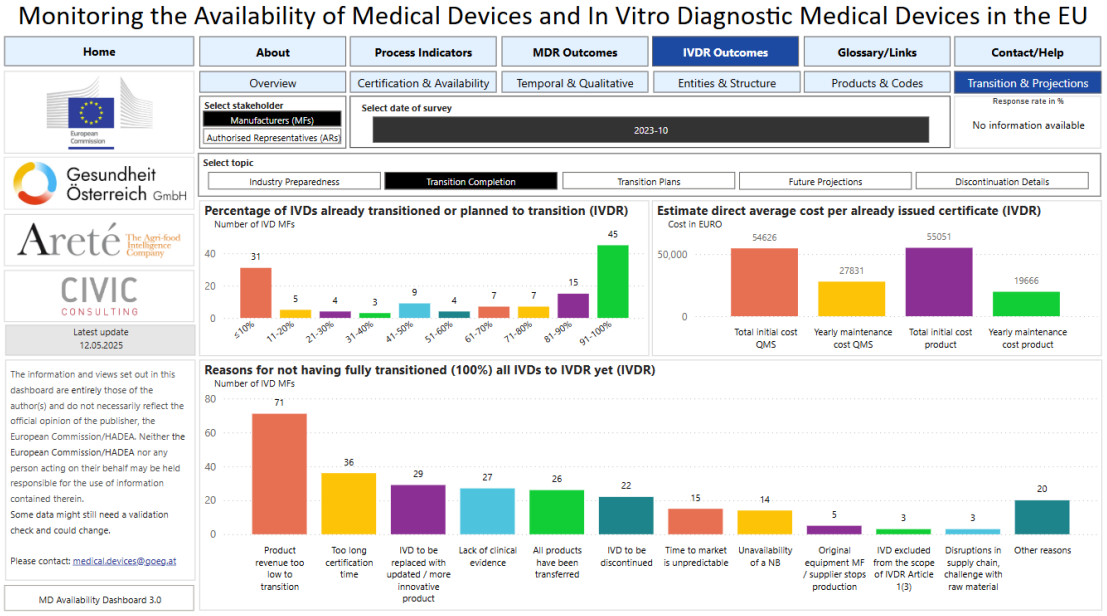

Figure 14: IVDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 22)*

Highlight of Figure 14; 45 manufacturers have 90-100% of IVDs already transitioned or planned to transition to IVDR whereas 31 IVD manufacturers are planning to transfer or had transfer less than 10% of IVDs. Also, the estimate direct average cost per already issued certificate is 54626 euros for total initial cost QMS and 55051eur for total initial cost product certificate. In addition, the most frequent reasons for not having fully transitioned to IVDR is due to i) product revenue being too low to transition ii) too long certificate time iii) IVD to be replaced with updated/innovative product.

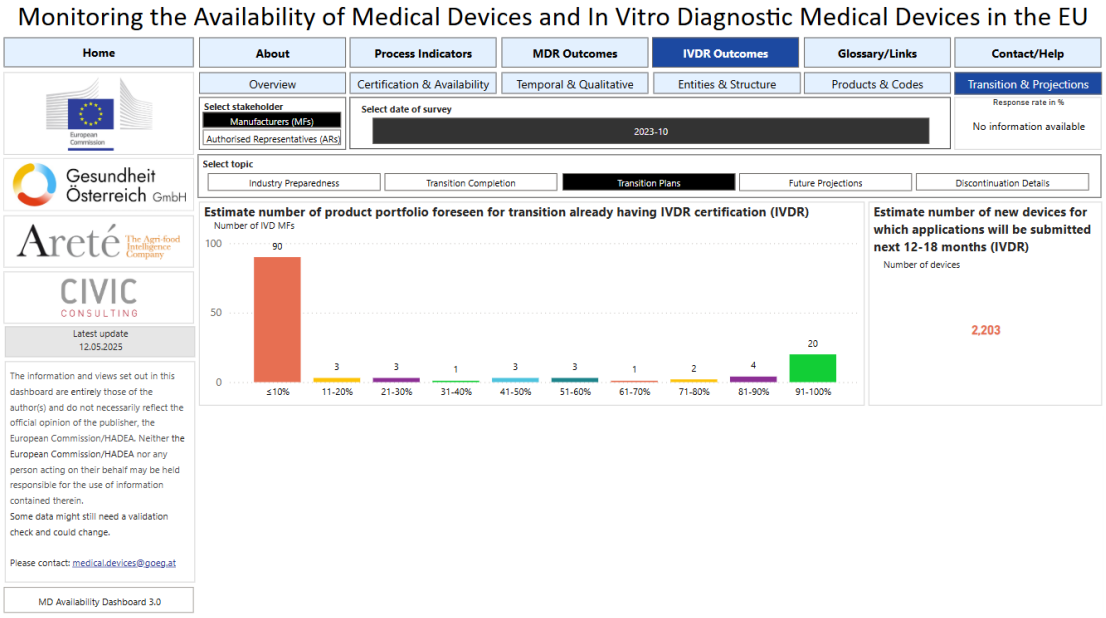

Figure 15: IVDR *Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 23)*

Highlight of Figure 15; 90 IVD manufacturers estimate that less than 10% number of product portfolio foreseen for transition already have IVDR certification. There are expectations of 2203 new devices for which applications will be submitted till the beginning of 2025.

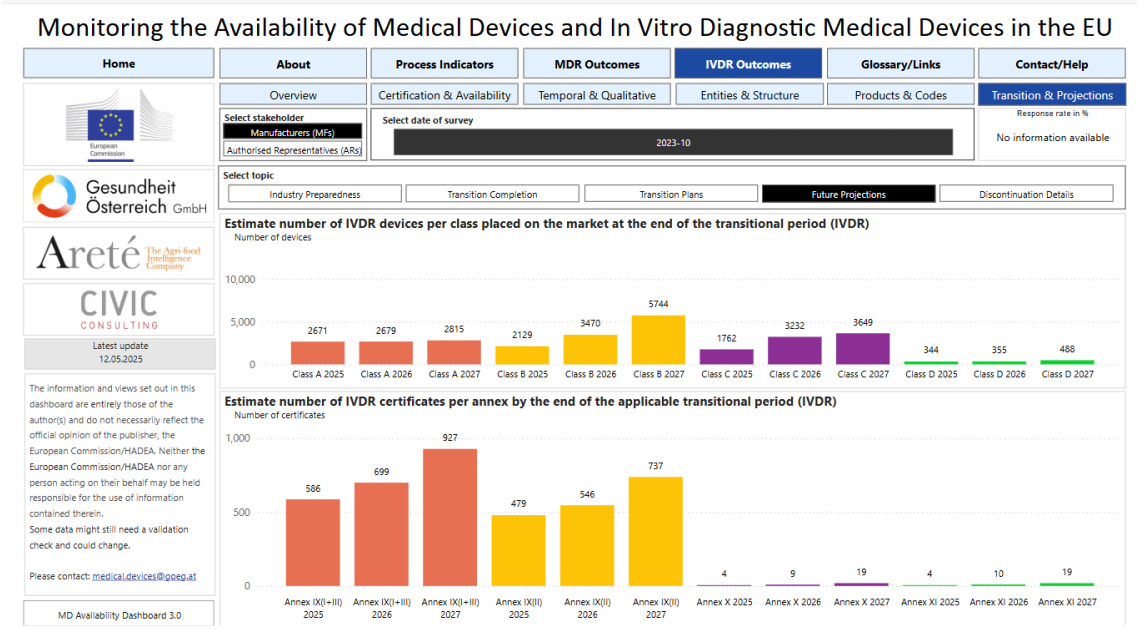

Figure 16: *IVDR Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 24)*

Highlight of figure 16; it is estimated that 5744 IVDR devices of class B placed on the market at the end of the transitional period in 2027.

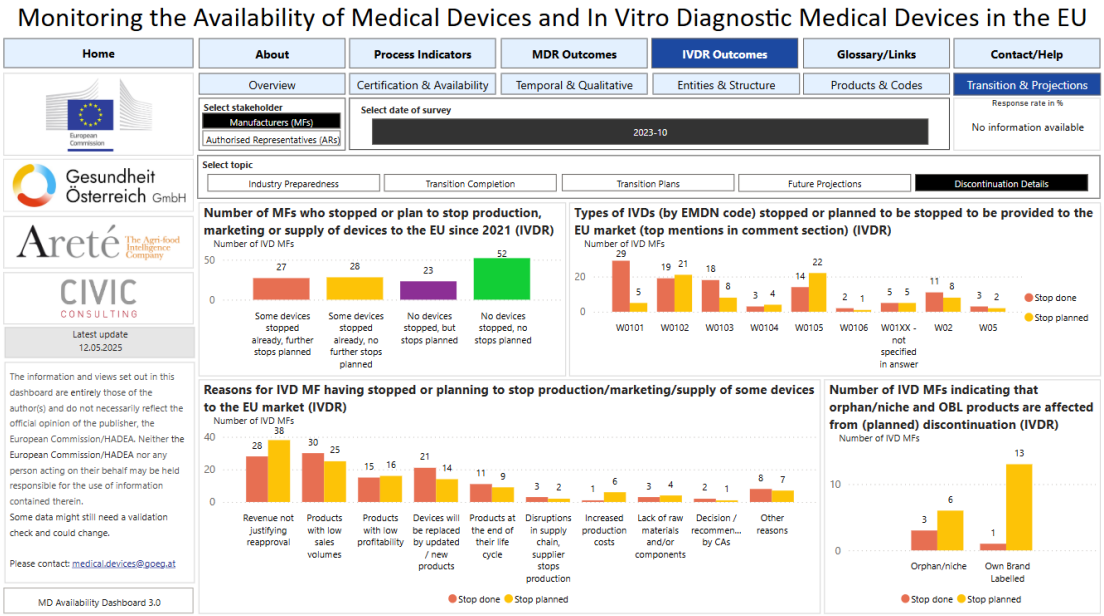

Figure 17: *IVDR Indicators for the monitoring availability of medical devices collected until October 2024, last update on May 12, 2025 (View of dashboard 25)*

Highlight of Figure 17; 27 manufacturers of IVDs stopped or plan to stop production, marketing or supply of devices to the EU since 2021. The most frequent reasons for IVD manufacturers having stopped or planning to stop production, marketing or supply of devices to the EU market are i) revenue not justifying re-approval ii) products with low sales volume iii) products with low profitability iv) devices will be replaced by updated/new products v) products at the end of their lifecycle.

2.9 Harmonized standards for presumption of conformity to IVDR/MDR

The European commission defines the harmonized standards as European standards developed by recognized European Standards Organizations (ESO) that include CEN, CENELE, ETSI per European commission´s request. Manufacturer´s and economics operators, Notified Bodies, can use harmonized standards to demonstrate product, services and processes comply with the appropriate EU legislation (European Commission, 2022). The guidance for implementation of EU product rules (2022/C 247/01) indicates that products manufactured in compliance with harmonized standards benefit from a ***presumption of conformity with the corresponding essential requirements of the applicable legislation***, and, in some cases, the manufacturer may benefit from a simplified conformity assessment procedure (in many instances the manufacturer's Declaration of Conformity, made more easily acceptable to public authorities by the existence of the product liability legislation) (European Commission, 2022).

In the specific case of medical technology, the European commission had published 6 amendments to the implementing decision (EU 2021/1182) on the harmonized standards for medical devices drafted in support of Regulation (EU) 2017/745 and 6 amendments to the implementing decision (EU 2021/1195) on the harmonized standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746. The Summary list of standards providing presumption of conformity to MDR and/or IVDR are presented in **Table 20**

Table 20: Summary List of harmonized standards to both IVDR and MDR. The color code indicates that the standard provides presumption of conformity to MDR (blue), IVDR (pink) and both IVDR & MDR (Green).

Legislation reference and ESO		Reference number of the standard	Title of the standard	Date of start of presumption of conformity
2017/745	CEN	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	July 19, 2021
2017/746 & 2017/745	CEN	EN ISO 11135:2014, EN ISO 11135:2014/A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)	July 20, 2021
2017/746 & 2017/745	CEN	EN ISO 11137-1:2015, EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)	July 20, 2021
2017/746 & 2017/745	CEN	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	July 20, 2021
2017/746 & 2017/745	CEN	EN ISO 25424:2019	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)	July 20, 2021
2017/745	Cenelec	EN IEC 60601-2-83:2020, EN IEC 60601-2-83:2020/A11:2021	Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	January 5, 2022
2017/745	CEN	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	January 5, 2022
2017/745	CEN	EN ISO 10993-9:2021	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)	January 5, 2022
2017/745	CEN	EN ISO 14160:2021	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)	January 5, 2022
2017/745	CEN	EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)	January 5, 2022
2017/746 & 2017/745	CEN	EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	January 7, 2022

Legislation reference and ESO		Reference number of the standard	Title of the standard	Date of start of presumption of conformity
2017/746 & 2017/745	CEN	EN ISO 13408-6:2021	Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	January 7, 2022
2017/746 & 2017/745	CEN	EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	January 7, 2022
2017/746 & 2017/745	CEN	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	January 7, 2022
2017/746	CEN	EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)	January 7, 2022
2017/746 & 2017/745	CEN	EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	May 12, 2022
2017/745	CEN	EN 285:2015+A1:2021	Sterilization - Steam sterilizers - Large sterilizers	May 17, 2022
2017/745	CEN	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	July 5, 2023
2017/746 & 2017/745	CEN	EN ISO 25424:2019, EN ISO 25424:2019/A1:2022	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)	July 5, 2023
2017/745	CEN	EN 455-3:2023	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	March 8, 2024
2017/745	CEN	EN ISO 10993-15:2023	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)	March 8, 2024
2017/745	CEN	EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)	March 8, 2024
2017/745	CEN	EN ISO 10993-18:2020, EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	March 8, 2024
2017/746 & 2017/745	CEN	EN ISO 11137-2:2015, EN ISO 11137-2:2015/A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	March 8, 2024
2017/746 & 2017/745	CEN	EN ISO 11607-1:2020, EN ISO 11607-1:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	March 8, 2024
2017/746 & 2017/745	CEN	EN ISO 11607-2:2020, EN ISO 11607-2:2020/A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	March 8, 2024
2017/745	CEN	EN ISO 17664-2:2023	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices (ISO 17664-2:2021)	March 8, 2024

Legislation reference and ESO		Reference number of the standard	Title of the standard	Date of start of presumption of conformity
2017/746 & 2017/745	CEN	EN ISO 13408-1:2024	Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)	October 9, 2024
2017/746	CEN	EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)	October 9, 2024

2.10 ISO 13485 Medical Device Quality Management Systems for regulatory purposes

ISO 13485 (ISO standards, 2016) is the international standard for quality management systems for medical devices for regulatory purposes. This standard was published in 2016 and prepared by the technical committee ISO/TC 210. This standard is important for manufacturers and suppliers of medical devices as it has the core requirements to ensure consistent design, development, production and delivery of medical devices that are safe and effective for the intended purpose. This standard has several benefits i) risk-based approach, it has risk management enhancement and provides a systematic method to identify and mitigate risk through the product lifecycle, ensuring patient and user safety ii) regulatory compliance, it enables organizations to recognize and meet regulatory requirements. Several countries have a nationally harmonized version of this standard, enabling the manufacturer and easier market access and global trade. iii)enhances reputation of organizations applying this approach and this enables operational efficiency to focus of processes that safeguard the medical device lifecycle iv) Global market access, a pre-market requirement is to have a quality management system, the certification to ISO13485 provides confidence that processes and objective evidence are established for the medical device design, developed, manufactured and delivered.

ISO 13485 is divided into 8 sections, see **Table 21** Section 4-8 describing requirements for the QMS appropriate for medical devices.

In Europe, the current harmonized standard for Medical Device Quality management system is EN ISO 13485:2016/A11:2021, the presumption of conformity can be claimed since Jan7, 2022 (for more information refer to **Table 20**).

Table 21: *Framework of Medical Device QMS for regulatory purposes (ISO13485, 2016)*

SECTION	REQUIREMENTS
I Scope	

SECTION	REQUIREMENTS
2 Normative Reference	ISO 9000:2015 Quality Management Systems- Fundamentals and vocabulary
3 Terms and Definitions	GHTF and ISO9000:201, ISO 14971:2007, ISO 11607-1:2006 definitions
4 Quality Management System	4.1 General requirements 4.2 Documentation requirements 4.2.1 General. 4.2.2 Quality manual 4.2.3 Medical device file 4.2.4 Control of documents 4.2.5 Control of records
5 Management Responsibility	5.1 Management commitment. 5.2 Customer focus 5.3 Quality policy. 5.4 Planning 5.4.1Quality objectives 5.4.2Quality management system planning 5.5 Responsibility, authority and communication 5.5.1Responsibility and authority 5.5.2 Management representative 5.5.3 Internal communication 5.6Management review 5.6.1 General 5.6.2 Review input 5.6.3 Review output
6 Resource Management	6.1 Provision of resources 6.2 Human resources. 6.3 Infrastructure 6.4 Work environment and contamination control. 6.4.1 Work environment 6.4.2 Contamination control
7 Product Realization	7.1 Planning of product realization 7.2 Customer-related processes. 7.3 Design and development 7.2.1 Determination of requirements related to product 7.2.2 Review of requirements related to product 7.2.3 Communication 7.3.1 General 7.3.2. Design and development planning 7.3.3 Design and development inputs 7.3.4 Design and development outputs 7.3.5 Design and development review 7.3.6 Design and development verification 7.3.7 Design and development validation 7.3.8. Design and development transfer 7.3.9 Control of design and development changes 7.3.10 Design and development files 7.4 Purchasing 7.4.1 Purchasing process 7.4.2 Purchasing information 7.4.3 Verification of purchased product 7.5 Production and service provision. 7.5.1 Control of production and service provision 7.5.2 Cleanliness of product, 7.5.3 Installation activities 7.5.4 Servicing activities 7.5.5 Particular requirements for sterile medical devices 7.5.6 Validation of processes for production and service provision. 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems 7.5.8 Identification 7.5.9 Traceability 7.5.10 Customer property. 7.5.11 Preservation of product. 7.6 Control of monitoring and measuring equipment.
8 Measurement Analysis and improvement	8.1 General 8.2 Monitoring and measurement. 8.2.1 Feedback 8.2.2 Complaint handling

SECTION	REQUIREMENTS
	8.2.3 Reporting to regulatory authorities. 8.2.4 Internal audit 8.2.5 Monitoring and measurement of processes 8.2.6 Monitoring and measurement of product 8.3 Control of nonconforming product. 8.3.1General 8.3.2 Actions in response to nonconforming product detected before delivery 8.3.3 Actions in response to nonconforming product detected after delivery. 8.4 Analysis of data 8.5 Improvement 8.5.1General 8.5.2Corrective action 8.5.3Preventive action ..

2.11 Maturity level models

Crosby (1779) is the precursor of the maturity levels related to quality. Crossby proposal is a roadmap to achieve higher levels of maturity, this model is called “Quality Management Maturity Grid” (QMMG), QMMG purposes is to help organizations to assess their QMS maturity in 5 levels: 1) uncertainty (the organization is unaware of quality, is reactive and it does not have any formal QMS process. 2) Awakening, in this second level, the organizations recognizes the importance of quality and takes action to improve it 3) Enlightenment, the third level has more understanding of “QMS principles” and implements structured quality improvement programs or projects with active growing commitment from management 4) Wisdom, the fourth level where organizations have comprehensive QMS and processes well established, quality improvement is the key of organization´s culture and there is strong focus on continuous improvement and the last level is 5) Certainty, characterized by a fully integrated QMS where quality is the strategic advantage and there is a sustained commitment to maintain high standards.

ISPE (2017) proposed a maturity model to assess data integrity in regulated companies. The aim of a maturity model is to be a management indicator to focus resources for improvement in quality, compliance and business practices. This model uses the concepts and approaches described in the Capability Maturity Model Integration (CMMI, 2002) to assess maturity in processes from a discipline with the aim to establish priorities for improvement and drive their implementation.

Alike medical devices, the pharmaceutical industry have in the literature more reference regarding pilot models utilizing maturity models, For instance, Fellows *et. al* (2022) benchmarked quality practices to advance the supply chain resilience among pharmaceuticals manufacturers utilizing a Quality Management Maturity (QMM). The information obtained when utilizing the QMS is useful to enable the availability of quality pharmaceutical products and to tackle supply chain disruptive events. QMM harnesses the risk-based approach to prevent shortage of drugs and a proactive supply chain management to ensure availability of drugs in the best interest of patients. Fellows and team conclude on one hand that the manufacturers with a mature quality management practice assessed by QMM have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. On the other hand, that QMM could complement surveillance inspection to inform the effectiveness of the QMS, as well as being a step forward performance-based regulation.

Recently, Maguire et al (2023) indicated that QMM assessments are used to determine three aspects of establishments i) the level of integration of quality systems and quality objectives with business and operations ii) the agility to respond to unexpected changes and iii) resilience in business and production process. The benefit of QMM is the identification of areas of improvement which can enhance capability and robustness in the overall supply chain.

3 Materials and Methods

This section describes the research methodology, research design, data collection and analysis methods.

3.1 Survey as a quality research method

Quality research methods are tools to explore complex phenomena and allow us to gain deep insight into human behavior experiences and social processes. A cost-effective quality research method is surveys which allow data collecting (Sheppard, 2020; Agius, 2013, Murphy, 2023). The advantage of the use of surveys is that i) broad reach, surveys can be distributed easily targeting respondents covering a large and diverse population which can enhance the generalization of the findings. ii) Efficiency, cost-effective tool that can be distributed relatively quickly and allows the collection of data in a short period of time. Iii) Standardization, the respondents receive the same questions, and they could provide standard answers this ensures consistency in data collection, making it easier to compare response (Shreppard,2020) iv) quantifiable data, the surveys can be designed with both open-ended and closed-ended questions. Closed-ended questions provide quantifiable data that can be analyzed statistically, meanwhile the open-ended questions allow for more detailed qualitative insights (Agius, 2013) v) Anonymity, survey can be designed to be anonymous which encourage respondents to provide more insight on sensitive topics (Murphy, 2023)

The disadvantage of survey in quality research i)) limit depth, unlike other quality methods like interviews and focus groups. The structured nature of surveys can restrict the richness of data as respondents may not have the opportunity to elaborate on their answers (Shreppard,2020 ii) response bias, respondents may provide socially desirable answers or may not fully understand the question, leading to response bias which affect the validity of the data collected (Agius, 2013) iii) low response rates, this limits the representativeness of the sample and the reliability of the findings (Murphy, 2023) iv)misinterpretation, if the question is not

well-understood, this can lead to inaccurate or incomplete data. v) Lack of interaction, unlike focus groups surveys limit the interaction between research and respondent from probing deeper into responses or clarifying ambiguities

3.2 Research Approach and design

This thesis is based on qualitative data collection, which is defined as the selection and production of linguistic material for analyzing and understanding phenomena subjective and collective experiences and the related meaning-making. Qualitative data collection also is applied to discover and describe issues in the field or structures and processes in routines and practices. The thesis was based on a flexible exploration study for data collection (Flick, 2018). This qualitative study is based on a survey/ interview with medical devices manufacturers. (Appendix 1) each question presents a standardized answer and has space to fill with thoughts, opinions or facts about the manufacturer's experience. No incentives were used for participants. Only reminders are sent to increase participation. The aim is often to arrive at materials that allow for producing generalizable statements by analyzing and comparing various exemplars, phenomena or cases.

The study had been divided into five different topics that allow us to explore the facts and experiences of organization´s related:

- Learning about the organization (7 questions)
- Learning about the organization s products (3 questions)
- Learning about the organization´s experience with IVDR/MDR (6 questions)
- Organization´s self- assessment of the maturity of your responsibilities under IVDR/MDR (1 question)
- Learning about the perception on IVDR/MDR (8 questions)

The survey was sent to different organizations, forums for manufacturers, targeting 1000 individuals which work in organizations that commercialized medical

devices and vitro diagnostics medical devices. The survey was sent though electronically through Webprol® through email, through RAPS forum, through TOPRA forum, invite with a QR code sent to different manufacturers forums in Finland. The questions and answers are presented in the chart with a percentage of responses for analysis. Furthermore, to get more insight on the influence of other factors, crosstabulation (Crosstab or contingency analysis) were used for comparing results of different respondent groups, the analysis was prepared with the statistic capabilities of Webprol® package for professional statistics.

4 Results of the study

4.1 Insights into study methods

The survey was delivered to over 1000 different individuals during December 2023-December 2024, having 466 different interactions with the survey, 55 individuals did not complete the survey and finally 16 complete surveys were obtained (**Figure 18**). Regarding, the other 55 respondents started to fill in the questionnaire but did not have deeper knowledge of the internal process of the organization and negotiations with notified bodies, as well potential respondents felt that their plans to transition into the new regulations were delayed to the transition grace period described in regulations EU 2023/607. 12/16 surveys had successful responses to the questions. 4 questionnaires were excluded because of the low quality of responses and reduced coverage of the questionnaire (less than 70% of the questions with objective answers)

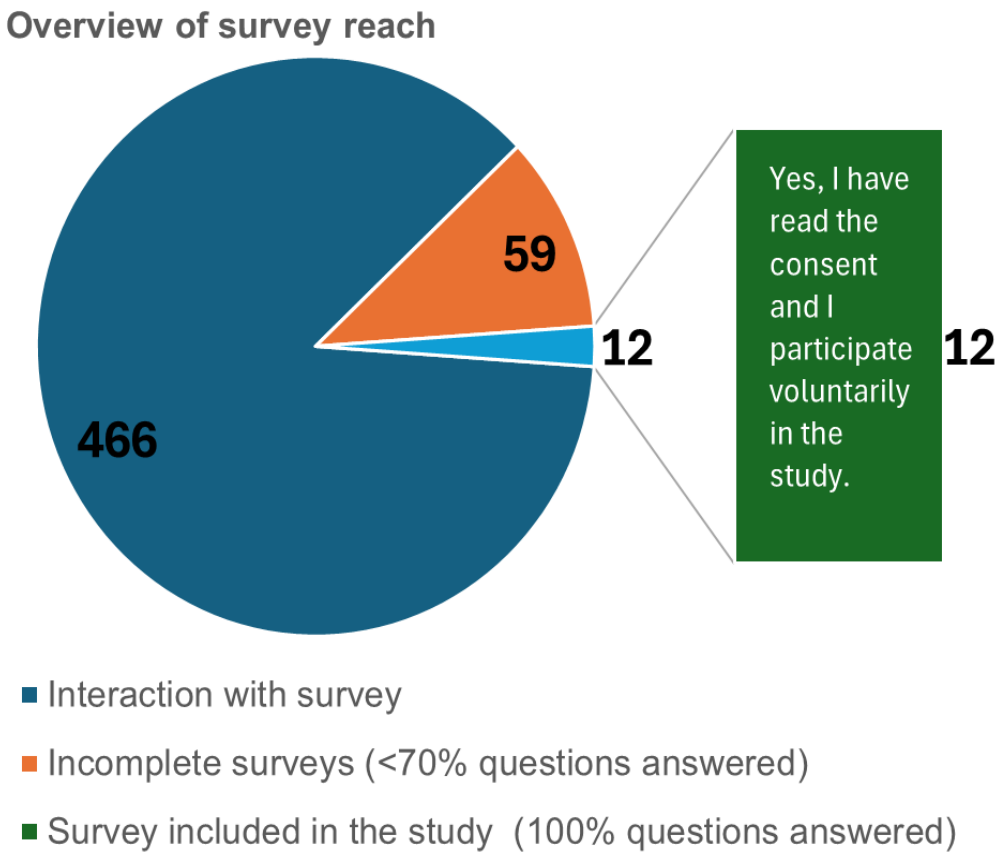

Figure 18: Reach of the survey.

The rate of response was 1,6%, this is because the extent of the questions required a deep understanding of the organization experience in the implementation of the regulations and the interactions with notified bodies which usually occur at the senior management level. To get a higher response rate, it is highly suggested to optimize the survey size and content (Booker, et al, 2021), though it would have been challenging to get a 360-degree view of the whole experience of organizations. Another way to increase the response rate is to include incentives like gifts, lotteries and monetary incentive (Bosch et al, 2024) though this would require funding to be able to provide incentives for the participants.

It is important to highlight that the legislation that supports IVDR/MDR had been changing providing extension times and companies are very cautious about the compliance status and the confidentiality as the topic of research is very sensitive.

4.2 Demographics of participating organizations

Position of participants (n=12). 11/12 (92%) participants belong to the management team. Furthermore 8/12 (67%) participants belong to senior management positions that lead the strategic directions of the organizations and 3/12 (25%) in middle management positions (***Figure 19***). About the size of the participant organization (n=12), 10/12 of respondents belong to organizations larger than 50 employees and 7/12 (58.3%) respondents belong to organizations larger than 250 employees, 3/12 (25%) belong to organizations with 50-250 employees and 2/12 belong to organizations with 10-50 employees (***Figure 20***). One limitation of the study is the low participant of start-ups or micro organizations (less than 10 individuals).

Next, ***Figure 21*** shows that the organizations are playing different roles in the supply chain. Principally, 12 (100%) are legal manufacturers and 8/12 (66.7%) also have distributor responsibilities, 3/12 (25%), inside the same organizations and smaller fractions assume as well Authorized representative and supplier roles. The participant organizations have operations mainly in North America (5/12 or 41.7%) and Europe (7/12 or 58.3%), see **Figure 22** to see the geographical region(s) where your organizations have operations.

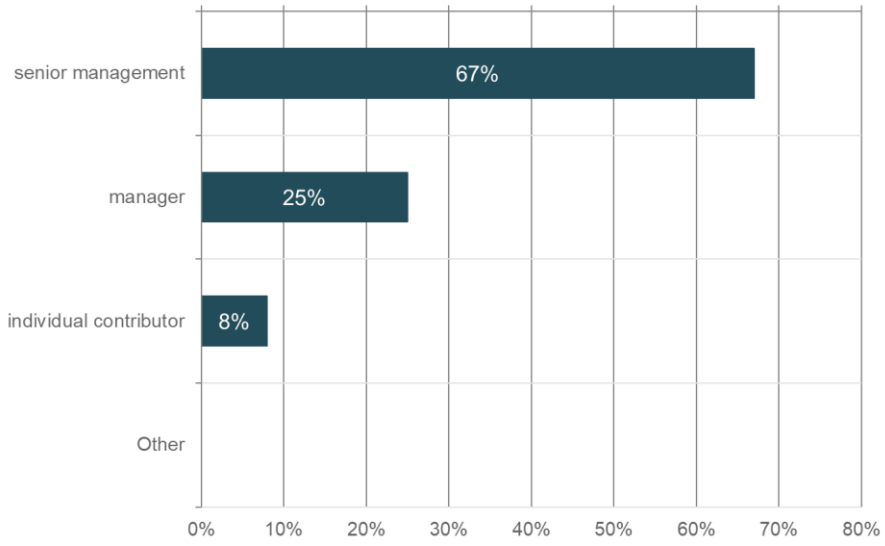

Figure 19: Position of participants *(n=12). 11/12 (92%) participants belong to the management team. Furthermore 8/12 (67%) participants belong to senior*

management positions that lead the strategic directions of the organizations and 3/12 (25%) in middle management positions.

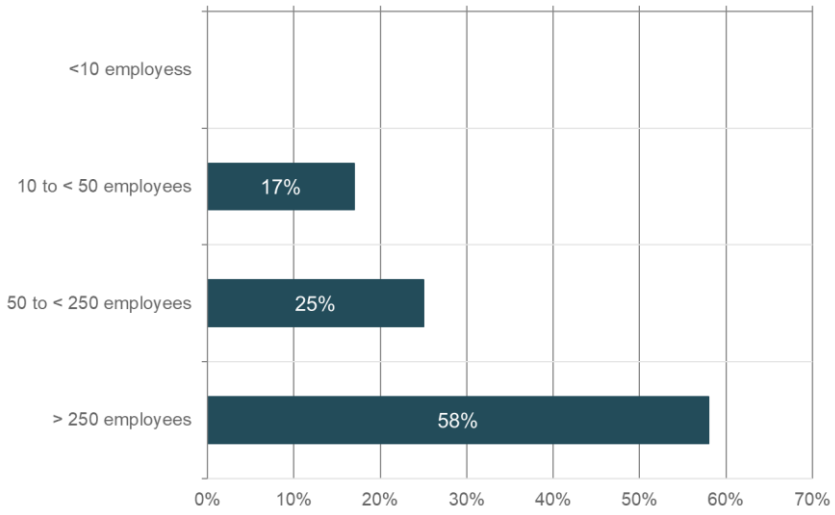

Figure 20: Size of the organization *(n=12). 10/12 of respondents belong to organizations larger than 50 employees and 7/12 (58.3%) respondents belong to organizations larger than 250 employees, 3/12 (25%) belong to organizations with 50-250 employees and 2/12 belong to organizations with 10-50 employees.*

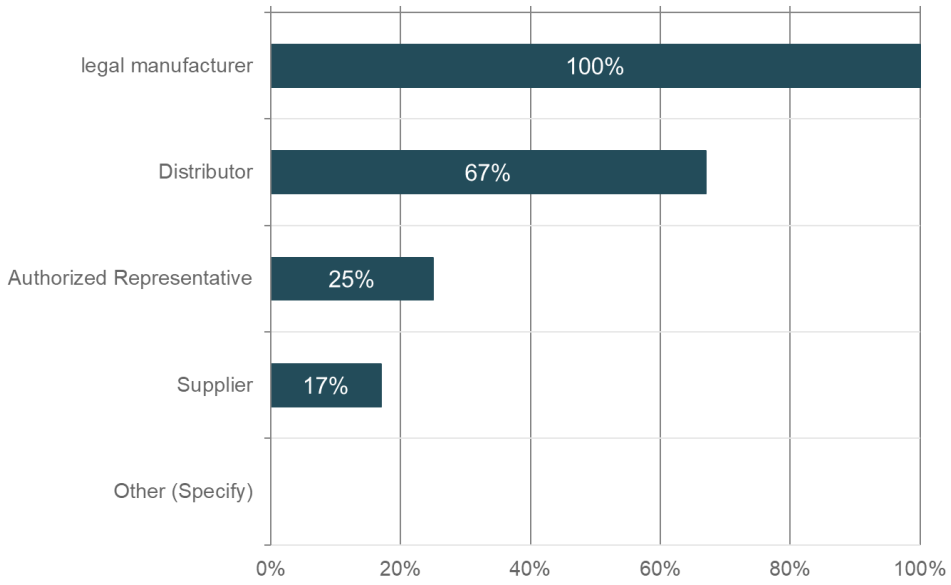

Figure 21: Different roles that the organizations play in the supply chain*. 12 (100%) are legal manufacturers, furthermore the organizations had multiple other*

roles like 8/12 (66.7%) also have distributor roles, 3/12 (25%) have Authorized Representative, 2/12 (16.7%) supplier roles.

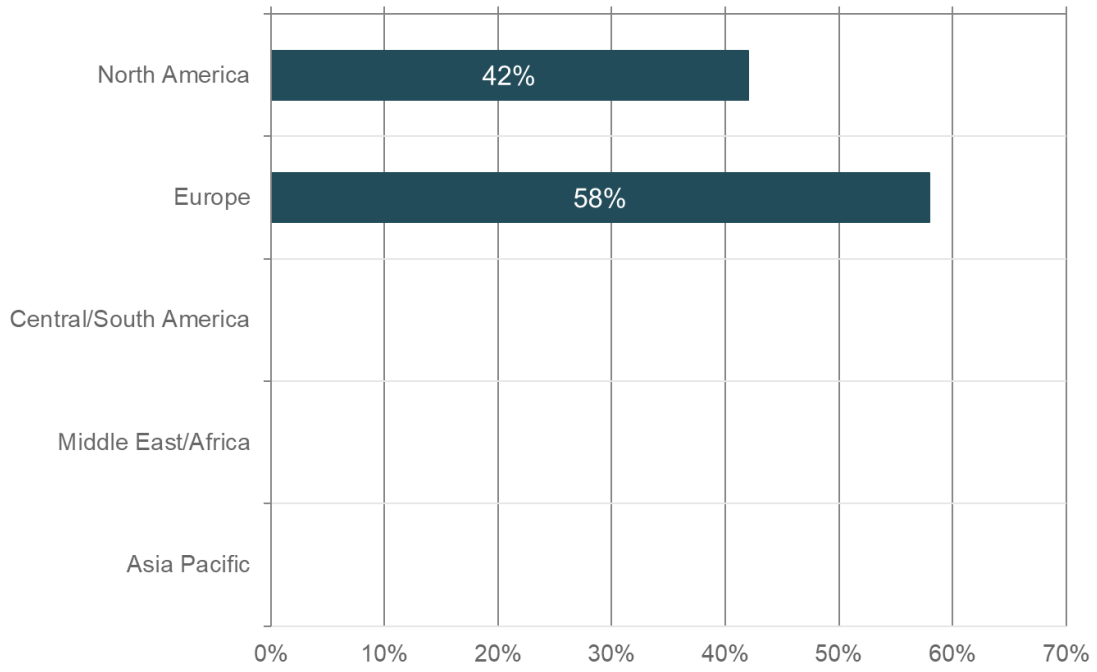

Figure 22: Geographical region(s) where your organization has operations. The main markets where the participant organizations have operations are in North America (5/12 or 41.7%) and Europe (7/12 or 58.3%)

4.3 Quality Management Systems

The participant organizations hold different and multiple certifications of the management systems,

Figure 23 shows that 12/12 (100%) certified to ISO13485, 3/12 (25%) are ISO 9001 certified, 3/12 (25%) is ISO14001 certified. 2/12 (16.6%) is ISO 27001 certified and 5/12 (41.7%) has MDSAP certification. In order to have further insight on the management certifications, the contingency analysis of Management Systems per Organization size was analyzed (**Figure 24**). The crosstabs shows that organizations with over 250 employees rely on other management systems to

maintain operations. The striking addition related to medical devices is the implementation of MDSAP program for a wider market access.

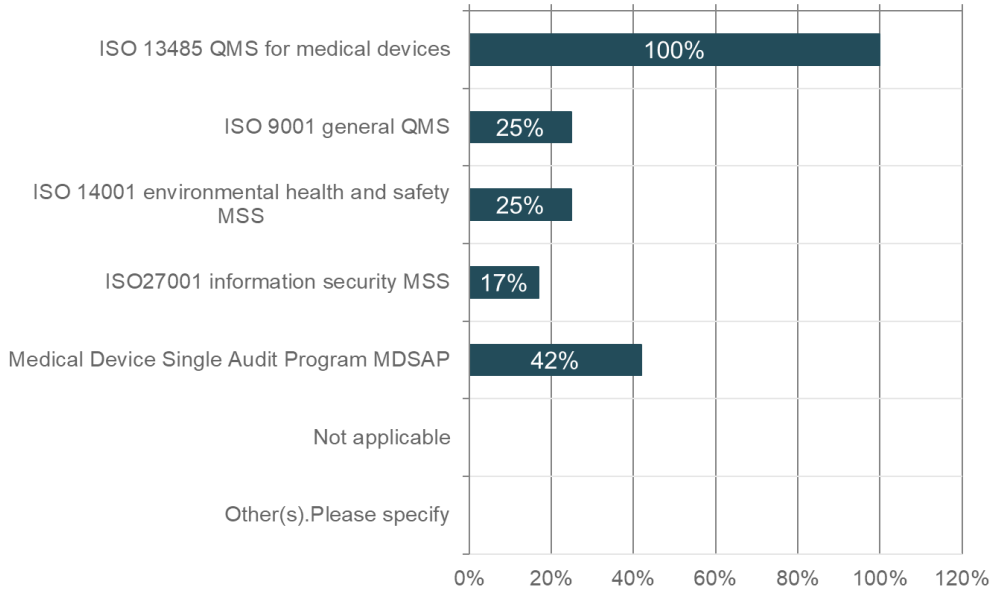

Figure 23: Certification of the management systems that the participant organizations hold. 12/12 (100%) certified to ISO13485, 3/12 (25%) is 9001 certified, 3/12 (25%) is ISO14001 certified. 2/12 (16.6%) is ISO 27001 certified, 5/12 (41.7%) has MDSAP certification.

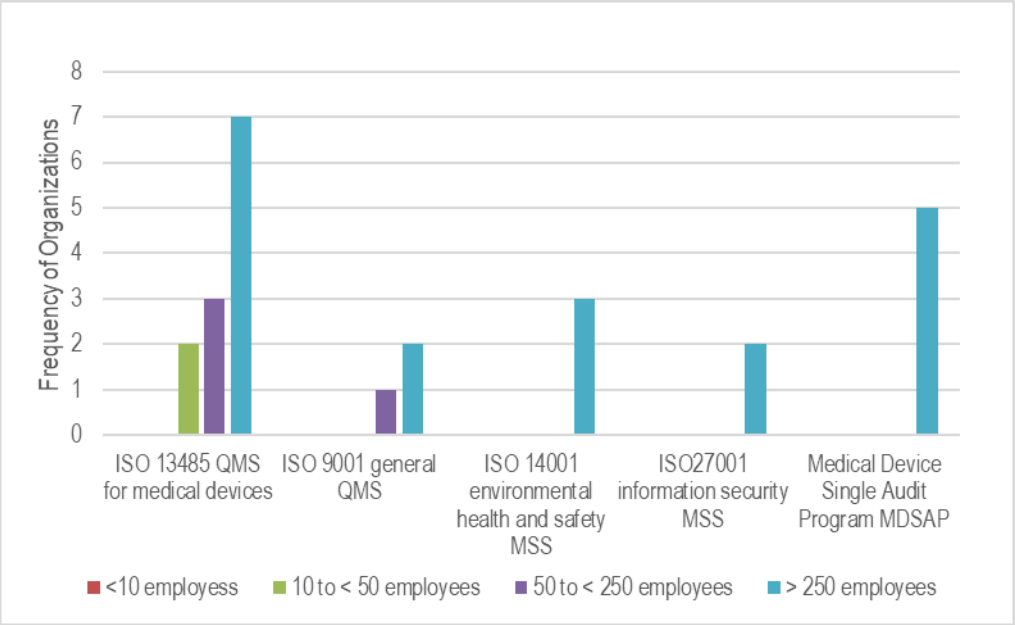

Figure 24 Crosstab of Management Systems per Organization size. Beyond ISO13485.The organizations with over 250 employees rely on other management systems to maintain operations. The striking addition related to medical devices is the implementation of MDSAP program for market access.

4.4 Global market product marketing authorizations

At least 50% of Medical device manufacturers that participated from the study have marketing authorizations around the globe. **Figure 25** shows the region(s) where the medical devices organizations are marketing their products or where they have regulatory responsibility. 12/12 (100%) place or make available products to the market in Europe. Additionally, 8/12 (66.7%) have presence in North America, 7/12 (58.3%) in Central/South America, 8/12 (66.7%) Middle East /Africa and 9/12 (66.7%) also in Asia Pacific.

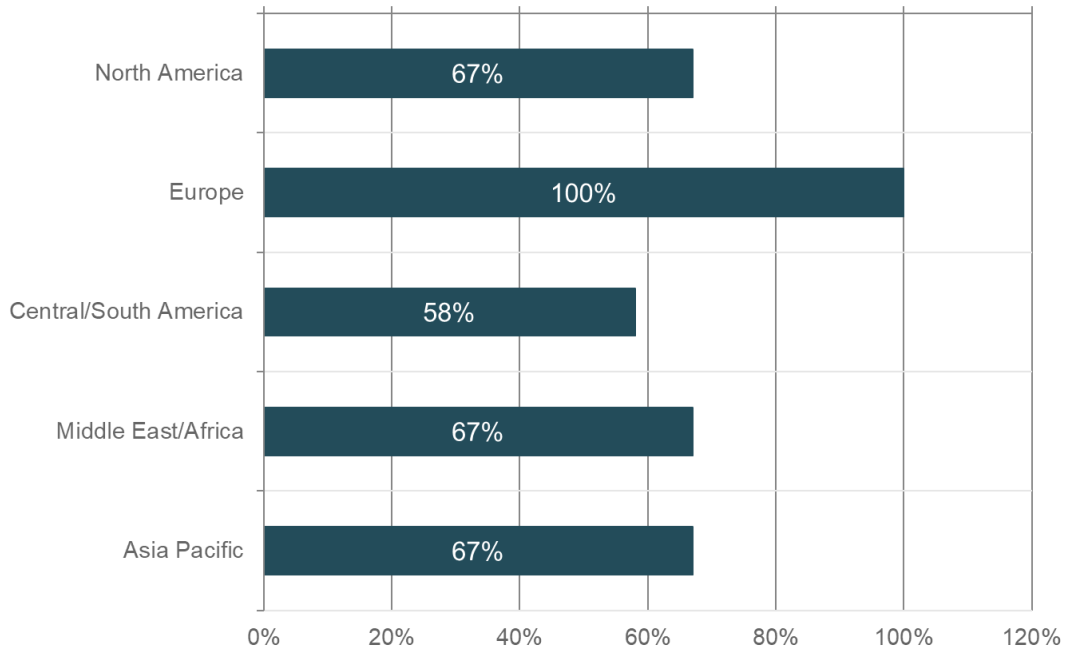

Figure 25: Region(s) where the organization's medical devices are marketed or where have regulatory responsibility. 12/12 (100%) place or make available products to the market in Europe. Additionally, 8/12 (66.7%) have presence in North America, 7/12 (58.3%) in Central/South America, 8/12 (66.7%) middle East /Africa and 9/12 (66.7%) also in Asia Pacific.

4.5 Regulatory profile of organizations from European perspective

The participant organizations sell either IVD or MD or both. 9/12 (75%) sell MD and 5/12 (42%) sell IVD (**Figure 26**). The profile of products is given by the distribution of the risk classes that participant organizations are placing in the market (See **Figure 27**) IVD class A 5/12 (41.7), IVD class B 5/12 (33.3), IVD class C 4/12 (33.3%), IVD class D 3/12 (33%), MD Class I 4/12 (33.3%), MD Class IIa 8/12 (66.7%), MD Class IIb 3/12 (25%) and Class III 2/12 (16.7%). In this study, the most frequent IVD risk class is class A and the most frequent MD risk class is IIa.

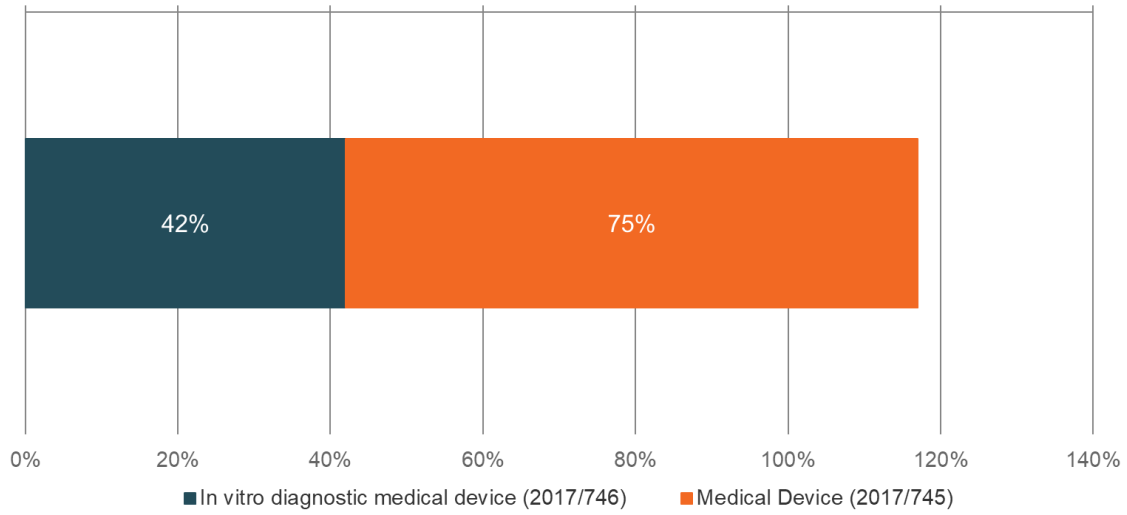

Figure 26: Scope of law applicable to both organizations. The participant organizations sell either IVD or MD or both. 9/12 (75%) sell MD and 5/12 (42%) sell IVD. Discussion

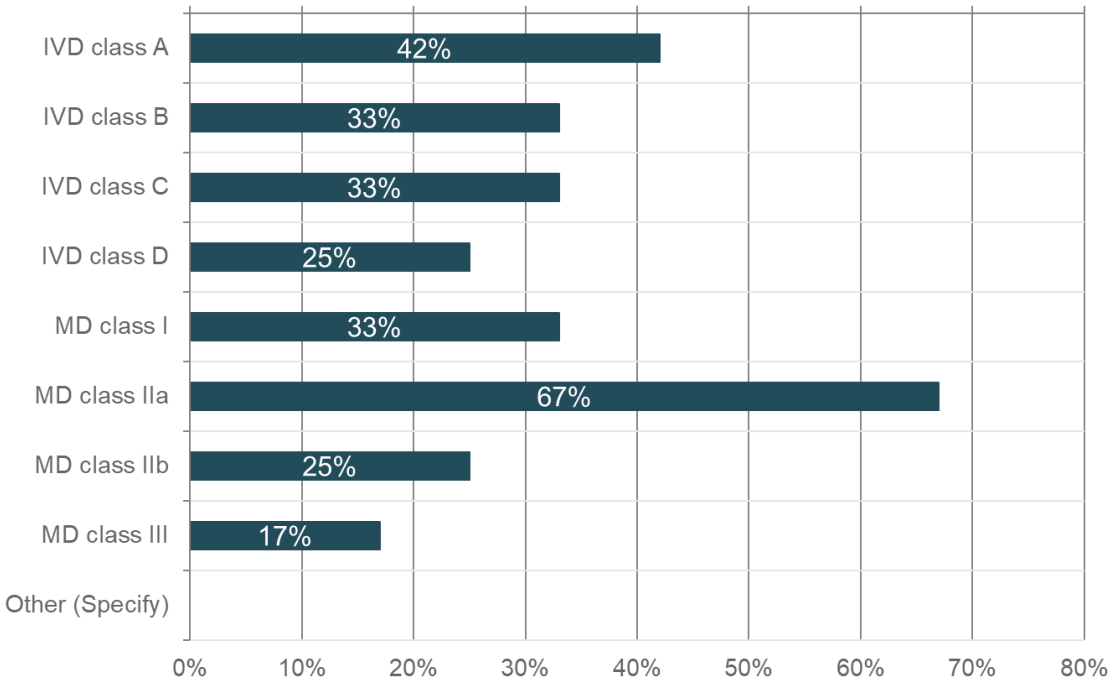

Figure 27: Distribution of the risk classes that participant organizations are placing in the market IVD class A 5/12 (41.7), IVD class B 5/12 (33.3), IVD class C 4/12 (33.3%), IVD class D 3/12 (33%), MD Class I 4/12 (33.3%), MD Class IIa 8/12 (66.7%), MD Class IIb 3/12 (25%) and Class III 2/12 (16.7%)

4.6 Estimate of the investment needed to fulfill European regulatory requirements

Implementation of the new regulations has a economic burden. **Figure 28** shows the gross estimate cost (Euro) for implementing the following IVD or MD regulatory requirements by the organization. The highlights are the implementation of several requirements do have an economical burden on the manufacturers. The expenditure is skewed towards 50 K-100K for several for requirements that provide objective evidence that product is safe and effective and surpassing the 100K where notify body involvement is required. In order to get further insight on the expenses versus company size, contingency analysis were preprepared. Figure 29 shows the crosstab of expenditure (euros) of different IVDR/MDR requirements that the manufacturer must fulfill shown by organization size. Different requirements implementation related to administrative requirements related to QMS implementation (Graphic A) and Notify Body involvement can climb up 100 Keur (Graphic C) and mandatory requirements for all classes like provide objective evidence that product is safe and effective and part of the technical documentation can easily have prices ranging 10-100 K (Graphics 29: B,D, E, F, G and H)

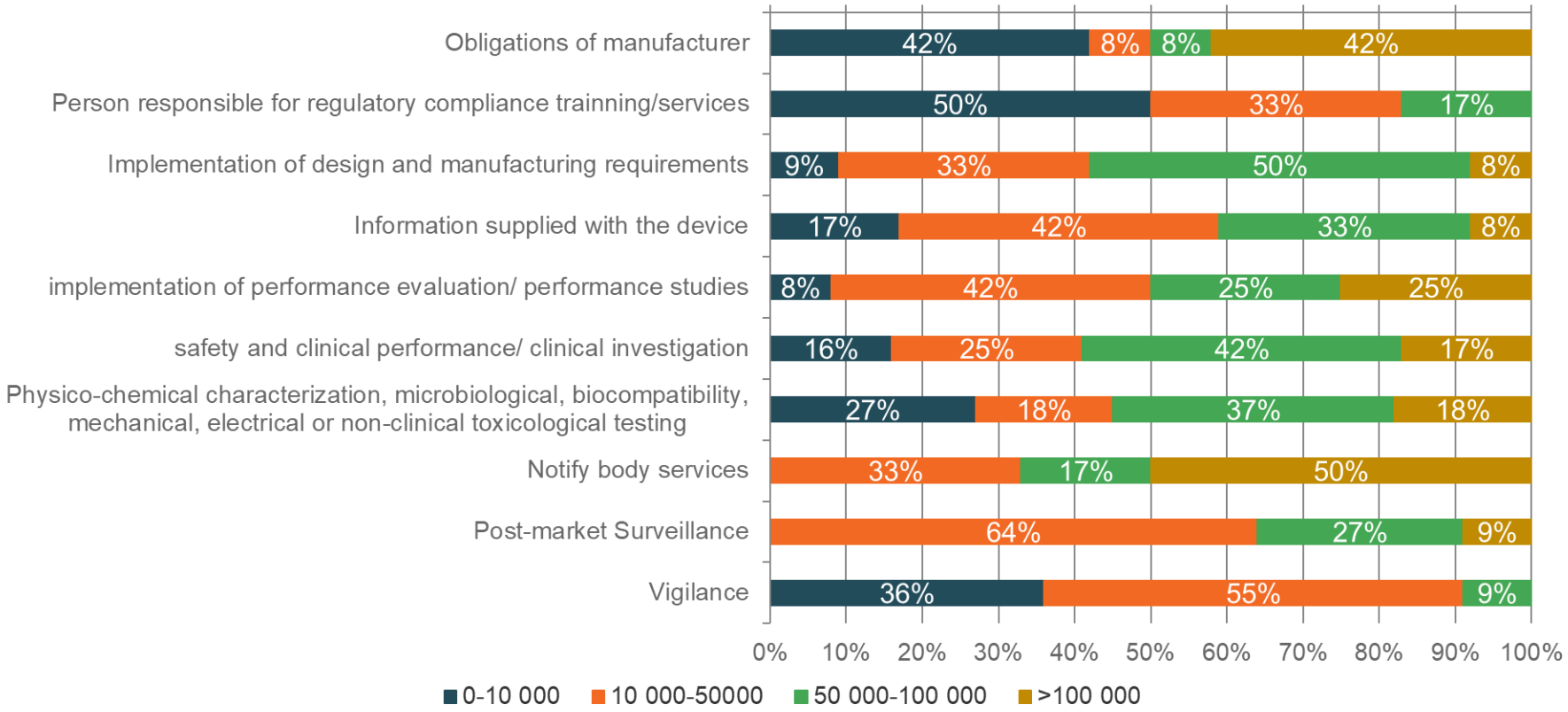

Figure 28: Gross estimate cost (Euro) for implementing the following IVD or MD regulatory requirements by the organization. The highlights are the implementation of several requirements do have a economical burden on the manufacturers. The expenditure is skewed towards 50 K-100K for several for requirements that provide objective evidence that product is safe and effective and surpassing the 100K where notify body involvement is required.

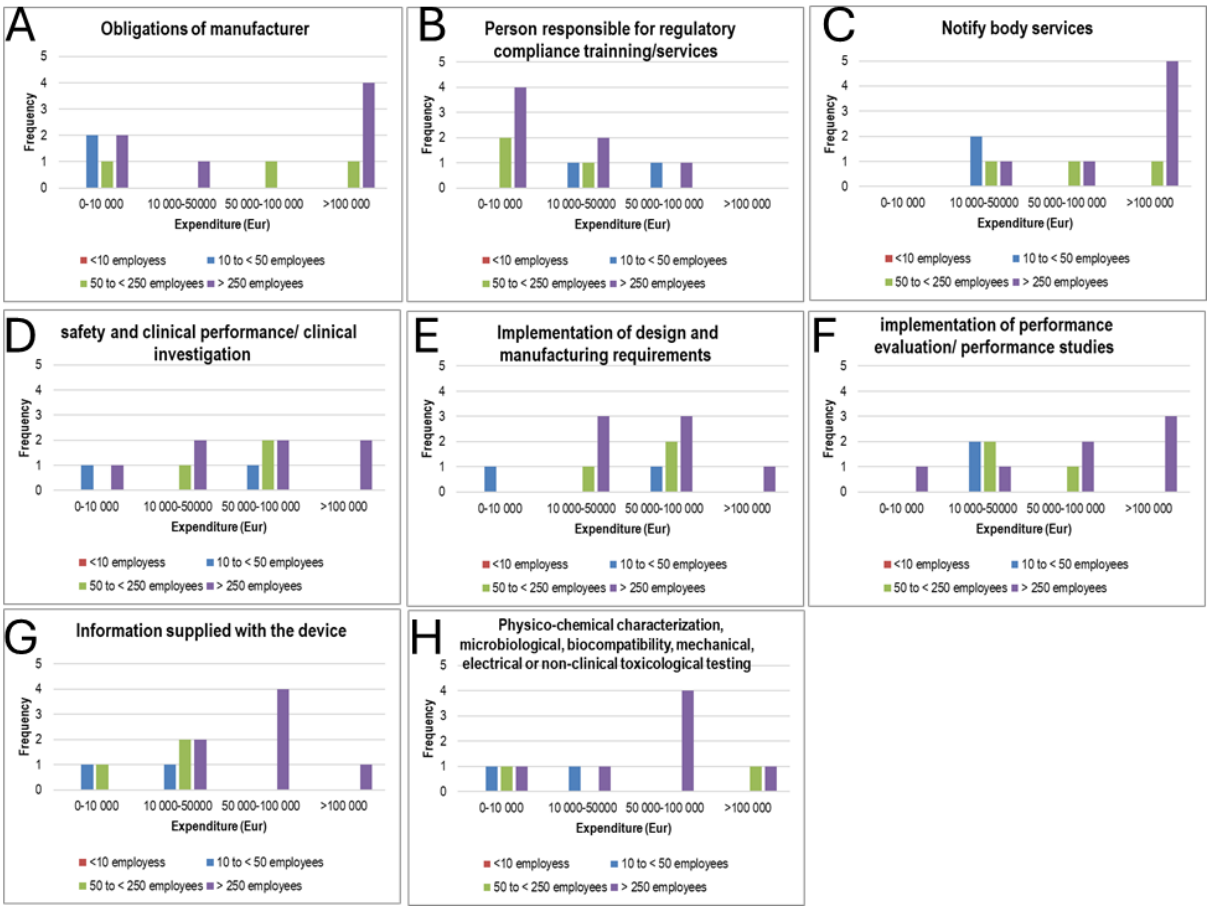

Figure 29: Crosstab of expenditure (euros) of different IVDR/MDR requirements that the manufacturer must fulfill shown by organization size. Different requirements implementation related to administrative requirements related to QMS implementation (Graphic A) and Notify Body involvement can climb up 100 Keur (Graphic C) and requirements that are required to provide objective evidence that product is safe and effective and part of the technical documentation can easily require 10-100 K (Graphics B,D, E, F, G and H)

4.7 Key Performance Indicators (KPI) determine the impact of IVDR/MDR in your organization

The open question presented to participants was “What kind of indicators (key performing indicators) are you utilizing to determine the impact of IVDR/MDR in

your organization? There were variable answers obtained by the different manufacturers, each organization utilized different sets of Key Performance Indicators to capture the impact of IVDR/MDR in their organization. **Figure 30** represents graphically the 7 different categories of KPI utilize to measure the impact of implementing of IVDR/MDR. The first category of KPI in pre-market KPI measures Time: Time to remediation to Technical File (TF) submission, Notified Body (NB) review timelines and NB review time. The second category of KPI in pre-market KPI measures Cost: Cost of external consultants and cost of internal workers. The third category of KPI in pre-market KPI measures Risk: Risk levels of short-term sales discontinuation. Whereas in post-market the KPI measure production and marketing performance, being the most common KPI was related to Sales, like Net sales and revenue. Finally, the KPI that can be measured during pre-market through post-market are Nonconformities by the NB, aswell as registrations and recertifications. Each organization is unique and the KPI selected by the organization provides useful information for decision making, the KPI most utilized is related to cost, sales and timelines.

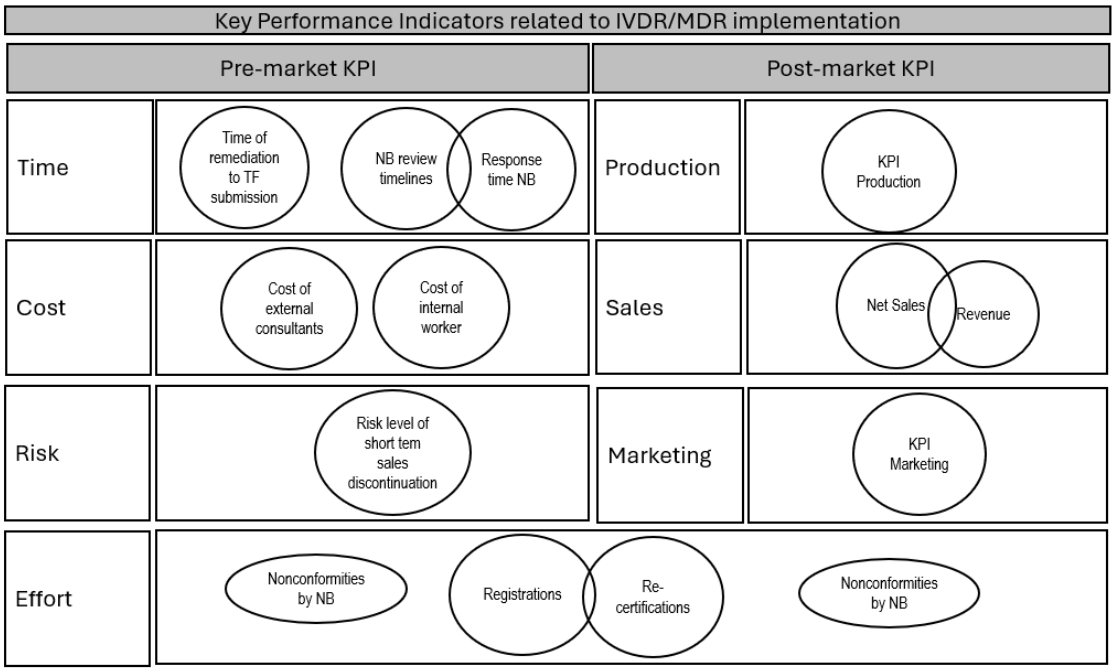

Figure 30 Key Performance Indicators that the organizations are utilizing to determine the impact of IVDR/MDR to their operations. These KPI were divided into pre-market KPI and Post-market KPI related to the implementation of IVDR/MDR.

4.8 Challenges that organizations experience

The challenges that an organization experiences can be divided into two categories. 1) challenges when implementing IVDR/MDR (**Figure 31**): in this category, over 50% of participants experience challenges in the following topics: product re-classification, management of resources and people, technical documentation and submissions, update of agreements with economic operators, product discontinuation. The other category includes 2) challenges while implementing IVDR/MDR **(Figure 32)**, in this category, the most common challenge (over 80% participants) is pressures related to pricing and profitability as well finance challenges related to funding, capital, credit, and financing. At least 50% of the participants are driving new product development efforts while implementing IVDR&MDR. Other less frequent challenges are related to regulatory changes in other markets, employee retention/recruiting. The least frequent challenges are increased competition and changing reimbursement environment.

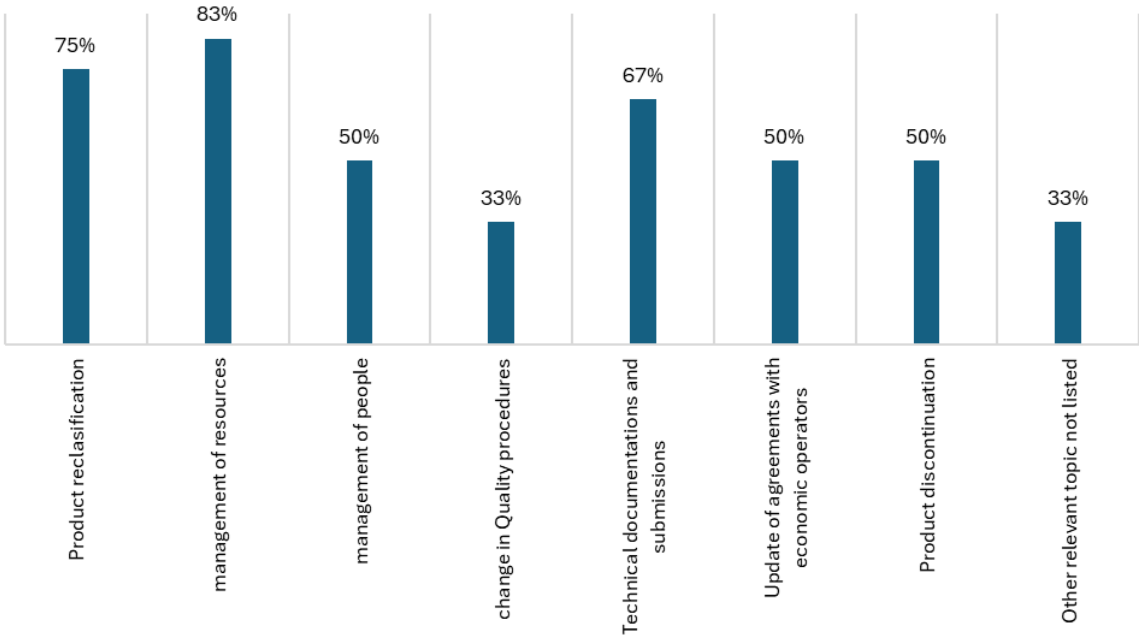

Figure 31: Challenges that organizations are facing implementing IVDR/MDR.

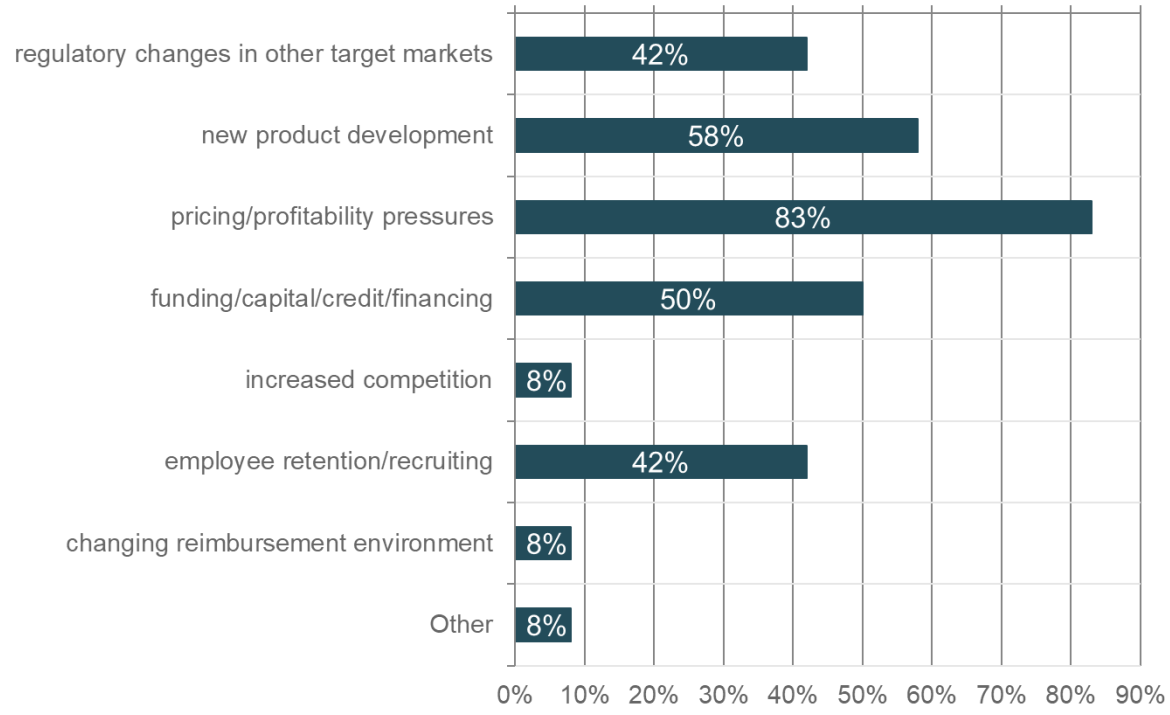

Figure 32: Challenges that organizations are facing while implementing IVDR/MDR. The biggest challenge indicated by 10/12 (83.3%) organizations is pricing and profitability pressures, followed by new product development 7/12 (58.3%), funding/capital/credit/financing 6/12 (50%), regulatory changes in other target markets 5/12 (41.7%), employee retention/recruiting 5/12 (41.7%), increased competition 1/12 (8.3%), changing reimbursement environment 1/12 (8.3%)

4.9 Maturity Assessment of requirements of Article 10 of IVDR/MDR by organizations

The maturity levels of the management system have 5 levels: Level1: undefined, uncontrolled, not monitored, no objective evidence. Level 2: partially defined, not formally controlled, not formally monitored, person dependent Level 3: defined policy and established processes, inconsistent application and inconsistent monitoring. Level 4: Defined policy and established processes, routine application and routine monitoring. Level 5: Defined policy and established processes, proactive and continuous improvement. In **Figure 33**, the self-assessment of the QMS maturity levels is shown. The maturity level assessment reveals a spectrum from

undefined and uncontrolled process (Level1) to proactive and continuously improving system (Level 5). Several organizations appear to concentrate at intermediate levels, indicating inconsistent application and monitoring of the processes. shows the self-assessment of maturity level required by article 10 of MDR/IVDR by the organizations deploying a high level of maturity. The core requirements with the strongest performance (at least 50% organizations), achieving QMS maturity level 5 are responsibility of management, risk management, Vigilance processes in place for reporting serious incidents and field safety corrective actions. The most frequent QMS maturity level is the level 4 with at least 50% of manufacturers on i) strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system ii) identification of applicable GSPR and exploration of options to address those requirements iii) performance evaluation, including post-market performance follow-up iv) product realization, including planning, design, development, production and service provision v)processes for monitoring and measurement of output, data analysis and product improvement.

Contingency studies were performed in order to have more insight on the maturity level versus the size of the organization (Figure 34). The crosstabs analysis revealed that organizations that have 50 or more employees in higher frequency maturity levels 4 and 5. The analysis also reveals that the requirements related to resource management (including control of suppliers and subcontractors require further development, being in level 3 the most frequent maturity level for bigger organizations. Also, maturity level 5 is the most frequent maturity level for responsibility of management and vigilance for larger organizations.

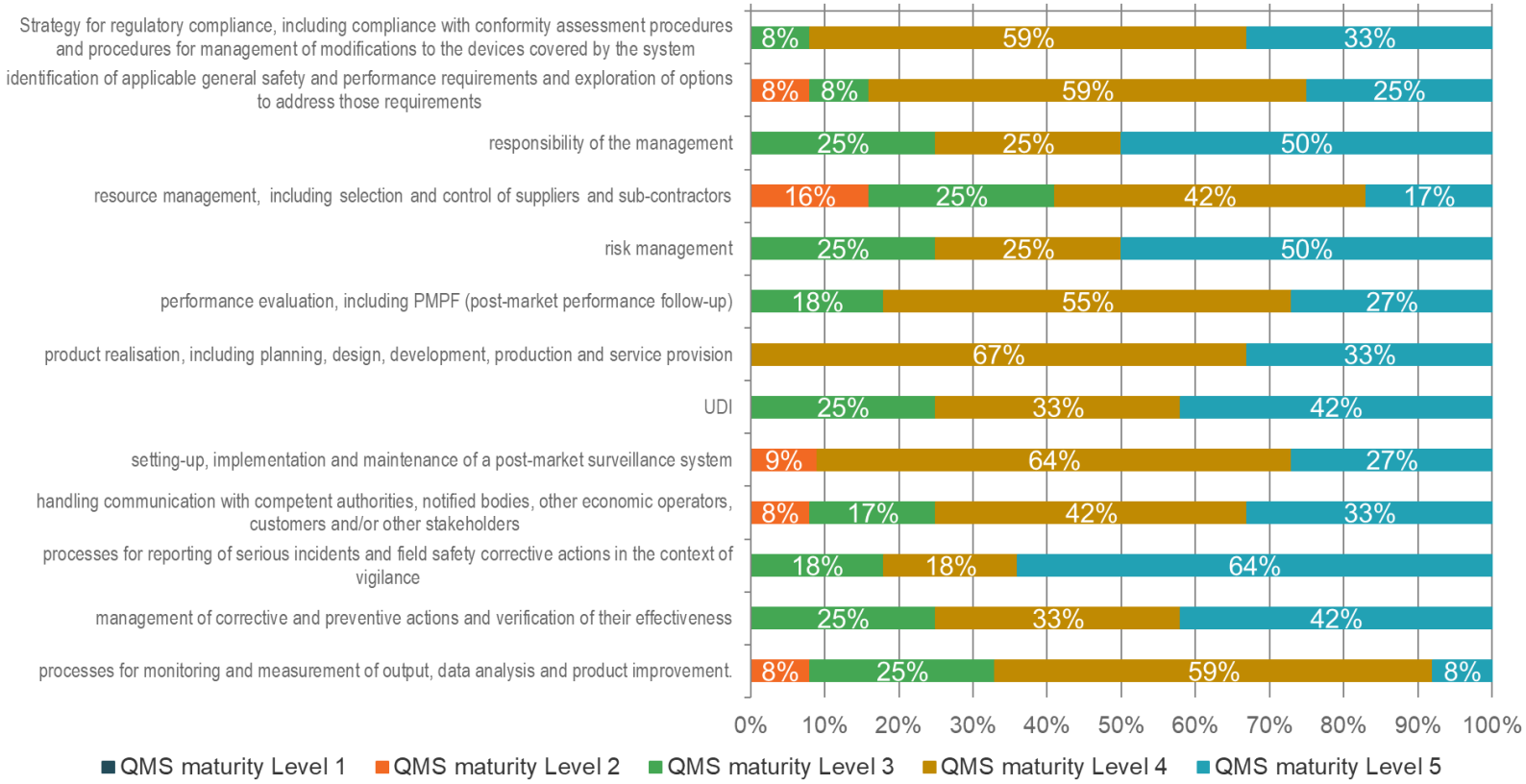

Figure 33: Outcome of the self-assessment of Maturity Level mapping of the requirements of Article 10 of IVDR/MDR by organizations**. Level1:** undefined, uncontrolled, not monitored, no objective evidence. **Level 2**: partially defined, not formally controlled, not formally monitored, person dependent **Level 3:** defined policy and established processes, inconsistent application and inconsistent monitoring. **Level 4:** Defined policy and established processes, routine application and routine monitoring. **Level 5:** Defined policy and established processes, proactive and continuous improvement.

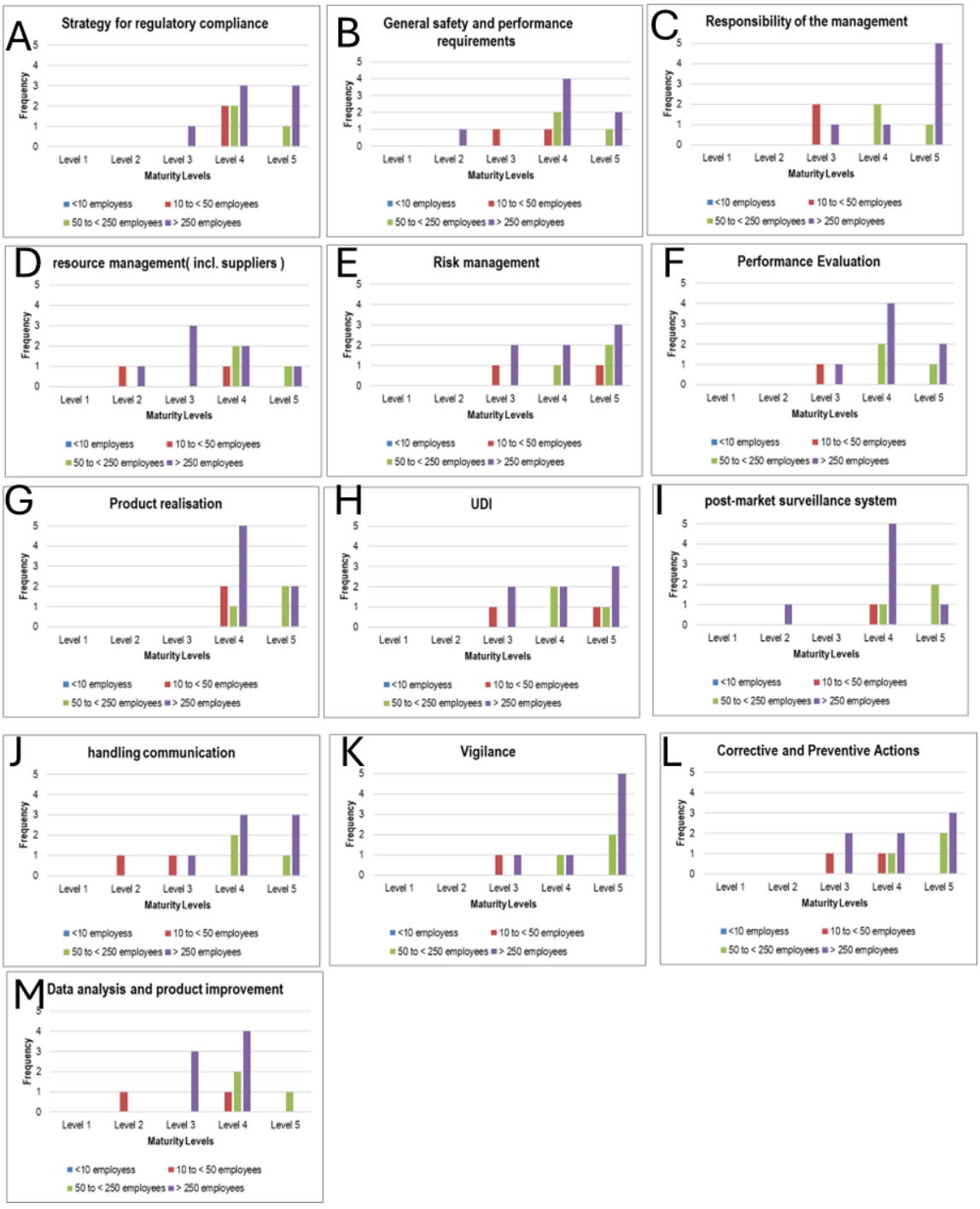

Figure 34: Crosstab Analysis of maturity level of requirements to fulfill Manufacturer´s obligation per Art 10 of MDR/IVDR versus the size of the organizations.

4.10 Perceptions of organizations on the Governance of the CE marking system

The participant organizations provided their perception to the question “The IVDR/MDR regulations aim to enhance safety, transparency, traceability, scrutiny of IVD/MDs in Europe whilst at the same time supporting innovation and protecting the EU market. Do you think that this objective will be achieved? Why? 6/12 (50%) disagree that IVD/MDR will achieve its objective, whereas 2/12 (16.7%) agree that the objective will be achieved (**Figure 35**). In addition, when asked Do you agree with the following affirmation “the CE marking system is efficient” Why? (**Figure 36**) Only 2/12 (16.7%) agree that the CE marking system is efficient. Whereas 5/12 (41.7%) is neutral and 5/12 (41.6%) disagree or completely disagree that the CE marking system is an efficient system. Next, the distribution of the organization´s opinions to the question: “We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes” shows that 11/12 (91.7%) of organizations agree (5/12 or 50%) or completely agree (6/12 or 50%) that there is need of a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes (**Figure 37**). Another graphics of the distribution of the organization´s opinions to the question: Do you agree with the following affirmation “the IVDR/MDR promote innovations, and they are connecting patients with the latest medical technologies” Why? Indicates that 4/12 (33%) not sure whereas 5/12 (42%) disagree and (3/12) 25% completely disagree that IVDR/MDR promote innovations (**Figure 38**). Also, the distribution of the organization´s opinions to the question: Do you agree with the following affirmation “IVDR/MDR need to include an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers” 11/12 (91.7%) agrees or completely agrees, whereas 0% disagrees or completely disagrees(**Figure 39**).

Moreover, the distribution to the question: Do you agree with the following affirmation “ the governance structure of IVDR/MDR is adequate” Why?. 2/12 (16.6%) agrees or completely agrees that the governance structure is adequate, 3/12

(25%) is not sure and 7/12 (58.4%) disagree or completely disagrees(**Figure 40**) Finally, the distribution of the organization´s opinions to the question: Do you agree with the following affirmation “There is need of an accountable Governance Structure consisting of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions” Why?. 6/12 (50%) agree or completely agree, whereas 5/12(41.7%) is not sure and 1/12 (8.3%) disagrees (**Figure 41**)

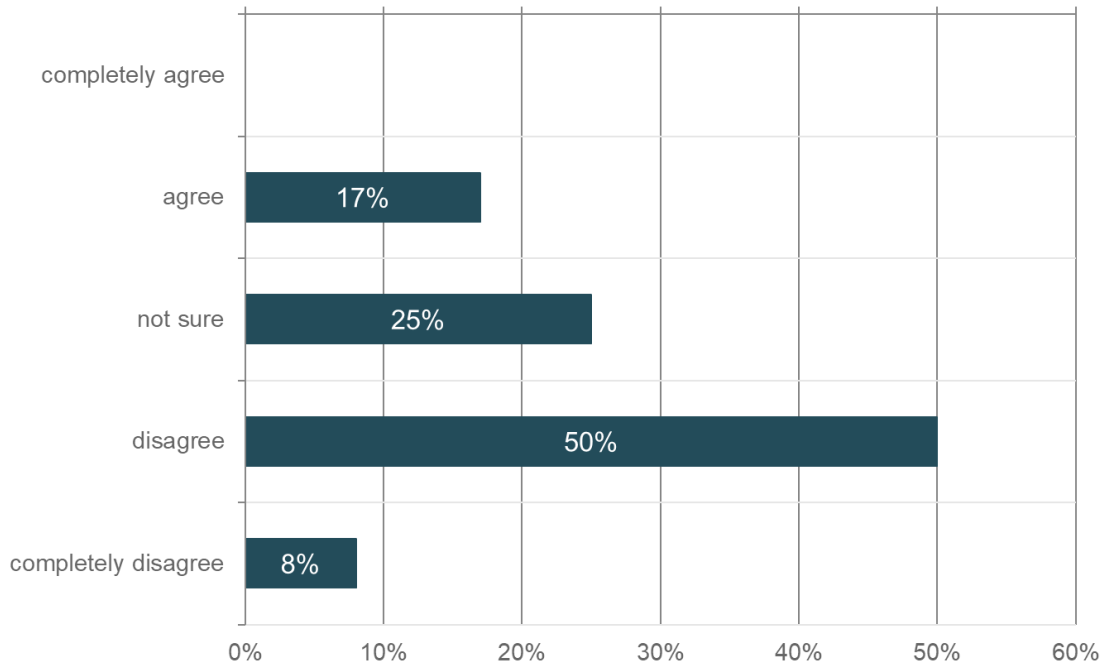

Figure 35: Distribution of the organization´s opinions to the question: “ The IVDR/MDR regulations aim to enhance safety, transparency, traceability, scrutiny of IVD/MDs in Europe whilst at the same time supporting innovation and protecting the EU market. Do you think that this objective will be achieved? Why? 6/12 (50%) disagree that IVD/MDR will achieve its objective, whereas 2/12 (16.7%) agree that the objective will be achieved

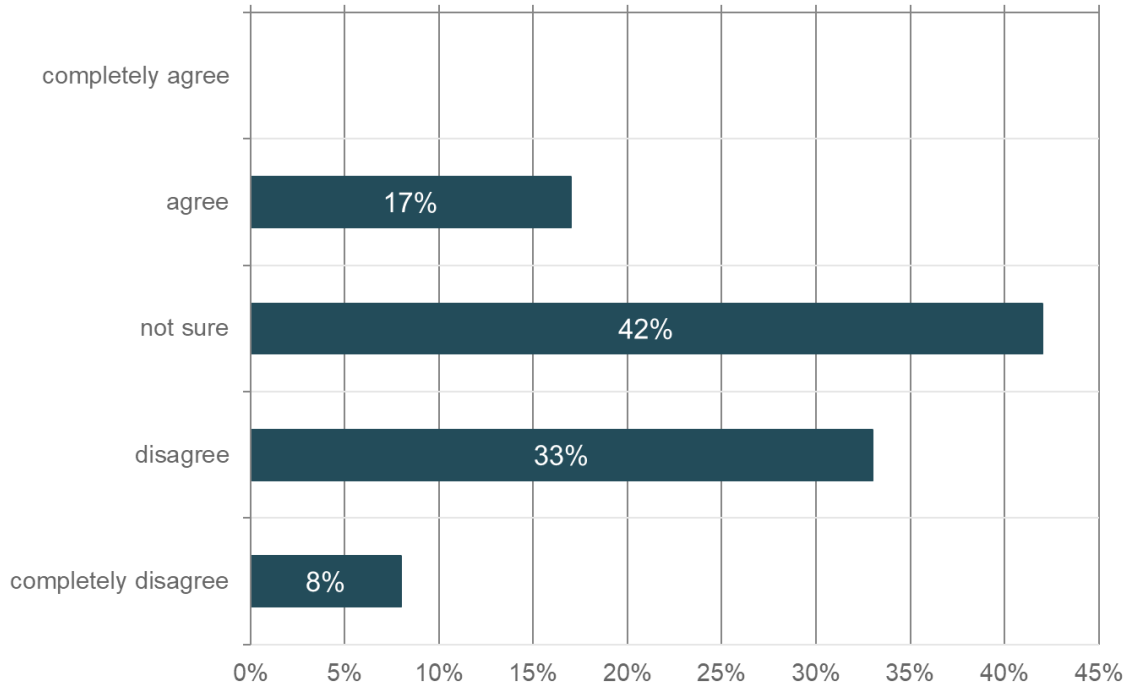

Figure 36: Distribution of the organization´s opinions to the question: Do you agree with the following affirmation "the CE marking system is efficient" Why? Only 2/12 (16.7%) agree that CE marking system is efficient. Whereas 5/12 (41.7%) is neutral and 5/12 (41.6%) disagrees or completely disagrees that the CE marking system is an efficient system.

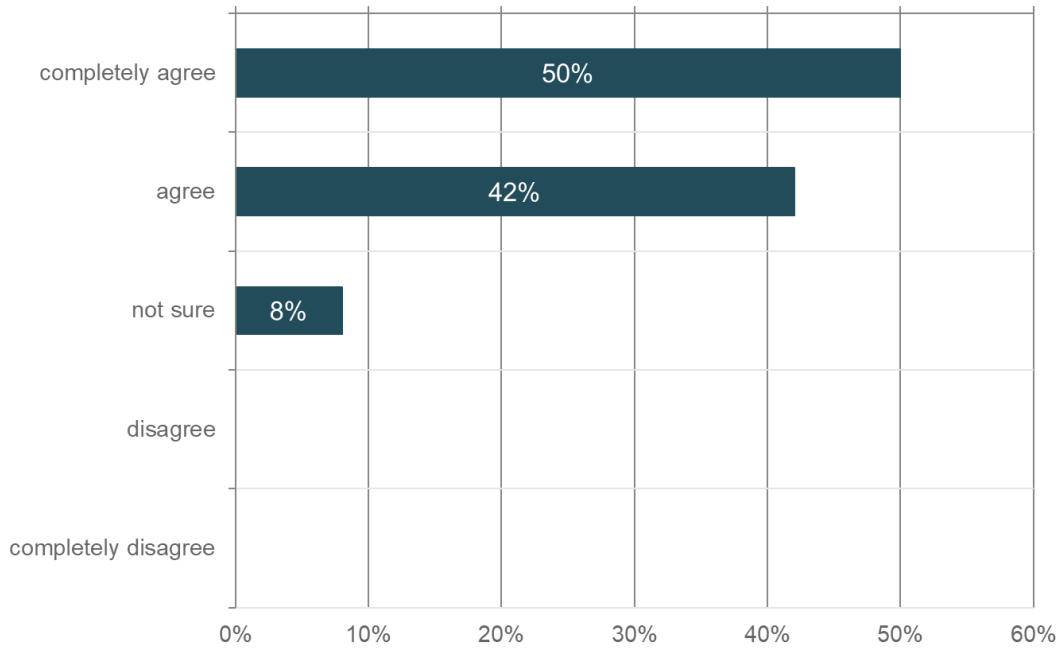

Figure 37: Distribution of the organization´s opinions to the question: "We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes" 11/12 (91.7%) of organizations agree (5/12 or 50%) or completely agree (6/12 or 50%) that there is need of a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes.

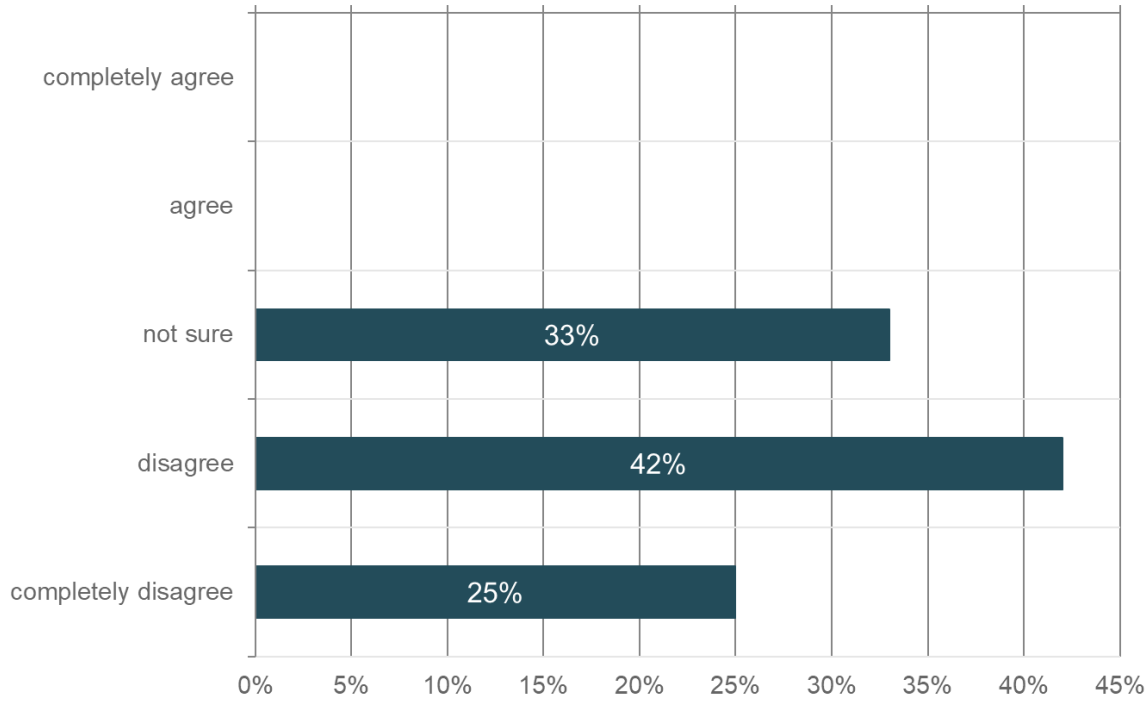

Figure 38: Distribution of the organization´s opinions to the question: Do you agree with the following affirmation "the IVDR/MDR promote innovations, and they are connecting patients with the latest medical technologies" Why? 4/12 (33%) not sure whereas 5/12 (42%) disagree and (3/12) 25% completely disagree that IVDR/MDR promote innovations

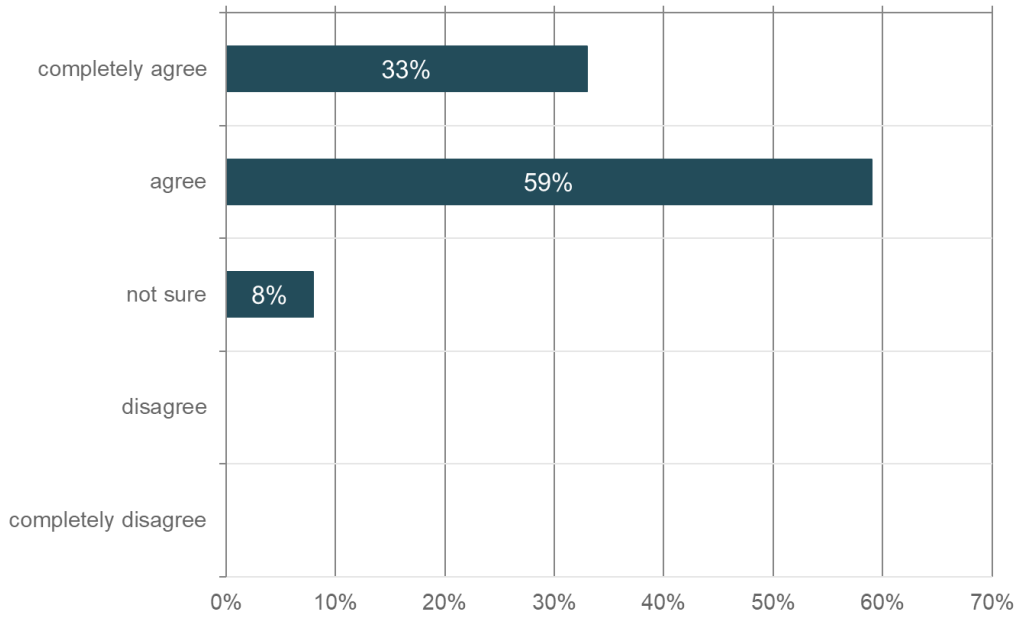

Figure 39: Distribution of the organization´s opinions to the question: Do you agree with the following affirmation "IVDR/MDR need to include an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers" 11/12 (91.7%) agrees or completely agrees, whereas 0% disagrees or completely disagrees.

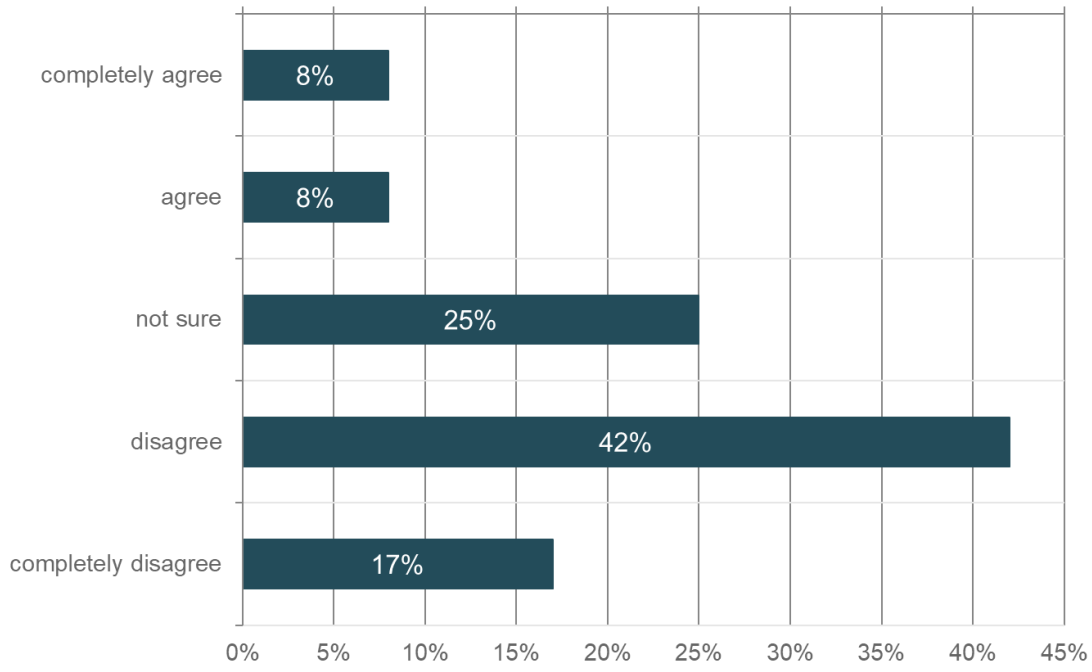

Figure 40: Distribution of the organization´s opinions to the question: Do you agree with the following affirmation " the governance structure of IVDR/MDR is adequate" Why?. 2/12 (16.6%) agrees or completely agrees that the governance structure is adequate, 3/12 (25%) is not sure and 7/12 (58.4%) disagree or completely disagrees.

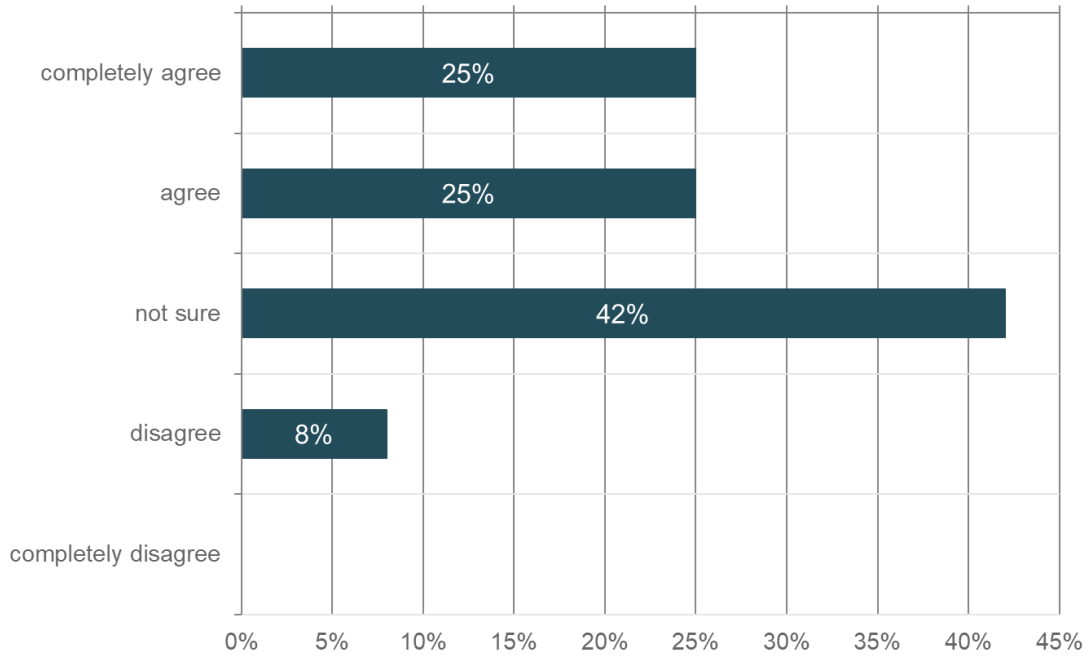

Figure 41: Distribution of the organization´s opinions to the question: Do you agree with the following affirmation "There is need of an accountable Governance Structure consisting of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions" Why?. 6/12 (50%) agree or completely agree, whereas 5/12(41.7%) is not sure and 1/12 (8.3%) disagrees.

5 Discussion

5.1 Assessing the validity of the research study

This quality research study aimed at recording and analyzing the experiences of different organizations which operate in the medical device arena under the regulatory framework to bring devices into the European market. The method used for quality data collection was a survey through a set of questions that enabled us to move towards data for meaning and representation (Flick, 2018).

The method utilized is considered adequate to research topics under study, the limitation of this study is the sample size (response rate). Though Bosch (2024) in his systematic study to improve response rate in probability-based online survey provides overview of different approaches that could be tested. In this study, the research was active with the delivery of the survey, sending reminders, contacting potential respondents through different platform's. The alternative not tested but that requires funding is to provide incentives.

There are limitations and gaps in the study, for example: i) there is need of a comprehensive representation: The study does not include insights from smaller organizations like start-ups or micro-organizations (less 10 count heads) with might face unique challenges related to IVDR/MDR. The challenge with the study is the hesitation of organizations to share compliance topics as they are part of the organization's reputation. Also, organizations want to protect their confidentiality and do not want to share internal information that can affect market perception or influence potential investors. Also, the study consists of a single time, a radiographic view of the organization. It would become more robust with the longitudinal Impact Analysis. The study lacks a longitudinal perspective to evaluate the implementation progress of MDR/IVDR overtime and see the maturity evolution of the processes in the management system. As the manufacturers and Notified Bodies gain experience, the impact of IVDR/MDR can be assessed having a long perspective in mind.

5.2 The impact of European medical devices regulations in organizations

Bruneo, *et al*, (2024) showed that biotechnology companies tend to exhibit higher risk profiles compared to the average firm in the market. The risk profiles in combination with the high scientific and regulatory complexity represent a high risk for investors (Ishikawa, 2024). Ishikawa (2024) highlights that there is need for strategic partnership work among entrepreneurs, policy makers and investors to address together the challenges to promote this business arena. This is important to enhance the growth of star-ups. This thesis lacked representation of start-up organizations (less than 10 employees) as they are not yet fully implemented QMS or are dealing with the regulatory and scientific burden.

All organizations in the supply chain have responsibilities under the European law for medical devices exemption for economic operations of the medical devices in Europe. The size or head count of the organization is not a variable that influences the implementation of IVDR/MDR. Organizations that want to sell devices globally need to make heavy investments to be able to launch products globally. In this context, Ishibashi (2024) examined the significance of the Medical Device Single Audit Program (MDSAP) as a regulatory reliance mechanism for medical device inspections/audits. MDSAP has been adopted by the regulatory authorities in Australia, Brazil, Canada, Japan and the United States. The MDSAP framework enables the recognition of third-party certification bodies to perform audits on medical device manufacturers on behalf of these jurisdictions. Next, Ishibashi (2024) highlights the potential of MDSAP as a model of regulatory reliance promoting more efficient and timely access to ´effective and safe medical devices´. This study showed that 42% of participants hold an MDSAP certificate and 100% ISO13485 concluding that MDSAP approach would be beneficial also as part of the conformity assessment/ registration pathway to enable EU manufacturers competitiveness.

5.2.1 Maturity of management system

The maturity levels approach has been used as a tool to diagnose and evaluate the level of compliance and readiness for ISO13485:2016 certification (Link & Canarozzo, 2024). Although tested in single companies and at a high clause level, this approach shows value to communicate areas of improvement. Unlike the approach of Link and Canarozzo (2024) the maturity assessment of this study focused on the evaluation of the requirements of QMS of already ISO13485:2016 certified organizations on the light of Article 10 of IVDR&MDR. The maturity assessment reveals that there are gaps existing to meet requirements laid down in Article 10 of both EU 2016/746 and EU 2016/745. The maturity levels varied between Level 2 through Level 5. Most of the processes concentrate between intermediate levels, indicating that there is need of monitoring systems, consistent application of the processes across the organization. The evaluation of maturity level has gaps related to the objective evidence evaluated to validate that the maturity level has been achieved. It is recommended to organizations who aim to increase their maturity level to meet readiness to meet QMS requirements per IVDR/MDR Article 10 to provide training and built capacity aswell as strength monitoring with fit-for-purpose key performance indicators. Also, to encourage the implementation of continuous process improvement methodologies. Another recommendation is to conduct further studies to understand how the organization size influences the maturity level and develop tailored strategies to support smaller organizations in meeting IVDR/MDR Article 10 requirements. Larger organizations reach high maturity levels, the availability of additional resources or guidance to align with regulatory requirements. In order to improve towards level of maturity 5, organizations need to have monitoring in place, which requires Key Performance indicators. Key performance indicators (KPI) are used to management decisions and help to improve performance of a specific dimension (Gebhard et al, 2023). Podgorski (2015) introduced the concept of KPI-based measurement of operational performance for a management system. Those KPI shall combined the characteristics: Specific, Measurable, Achievable, Relevant. Finally, Picozzi et all (2024) studied a pool of KPI to increase awareness of the

economic value, evaluating the performance of operational units, and refining processes like the maintenance process. Picozzi et all (2024) findings suggest that these KPI not only support continuous improvement but also serve as a foundation for leveraging business intelligence capabilities.

5.2.2 Challenges Experienced with IVDR and MDR

Mc Grane et al (2023) indicates that regulatory environment is perceived as a barrier for regulated industries compared to unregulated ones. Regulatory requirements that companies have to adhere to become “bottlenecks” in project management initiatives, continuous improvement projects and engineering changes. Regulatory requirements had to be fulfilled even when straight-forward methodology like “define-measure-analyze-improve and control” (DMAIC) are employed.

All organizations aiming to place or maintain their devices in EU had a learning curve by all stakeholders around IVDR/MDR.

There is a broad consensus that the regulations for IVD and MD are affecting the availability of medical care. In a open letter written on behalf of the European Medical Technology industry to the European Commission (September 2023) indicates that the current regulatory framework is “*unpredictable, complex, slow and costly*”. Hence, there is need of intervention to address systemic issues that will hinder medical technology access to patients and health system in Europe. (Here write your results) and compare them to the letter.

The 7/12 organizations that participated in the study have operations mainly in Europe and North America. They play different roles in the supply chain like Legal Manufacturer, Local Representative, Distributor and Supplier. The target market of these organizations include North America, Europe, Central and South America Middle East and Africa and Asia Pacific.

The participant organizations are manufacturing and distributing all risk classes of devices ranging from IVD A-D and MD class I, IIa, IIb and III.

One attribute that allows these organizations to have an already mature quality management system is the implementation of ISO13485 and in addition multiple ISO certificate like ISO9001, ISO27001, Medical Device Single Audit Program.

The gross estimate for implementation requirements by MDR/IVDR ranges from 50 000-100 000 eur for Notify Body Services, followed by implementation of design and manufacturing requirements and obligations of manufacturers.

MedTech Europe (2024) in their IVDR&MDR investigation reports a significant increase in the cost burden for manufacturers. Cost for Clinical evaluation or performance evaluation, Post-Market Surveillance (PMS), and certification have all risen substantially while national reimbursement for medical technologies have not. For over half of IVD manufacturers, costs associated with Technical Documentation Assessment (TDA) have doubled and clinical evaluation costs have similarly increased for MD manufacturers. Furthermore, there is considerable int variability in these costs exists, likely due to differing practices across Notified Bodies. This variability, in turn, impacts on the overall cost structure for manufacturers. The issues are particularly accentuated for SMEs and again for orphan devices (although any type device could be impacted by the cost and timelines complexity). Perhaps most concerning is the additional burden of internal costs, maintenance, and re-certification. These costs, accumulated over the course of a device's life cycle, outweigh the initial certification fees. By the end of the five-year certification cycle, IVD manufacturers are likely to spend approximately 70% more, while MD manufacturers will spend 50% more on maintenance and re-certification, not including full-time equivalent (FTE) costs. This financial burden, exacerbated by inefficiencies and administrative complexity, places undue strain on manufacturers without clear patient benefit. Furthermore, the financial and regulatory burden extends beyond Europe, potentially affecting global markets that rely on European certification (MedTech, 2024).

In this study, the challenges experienced by the organizations are product classification, management of resources and people, changing in quality procedures, technical documentation and submissions. Update agreements with economic

operators. Other challenges that are common to all manufacturers is pricing/profitability pressures (83%), regulatory changes in other target markets (42%), new product development (58%), funding/capital/credit/financing (50%) and employee retention/recruiting (42%) other minor aspects included increased competition (8%) and changing reimbursement environment (8%)

MedTech (2024) indicated that the overall, significant challenges remain and should be tackled in the areas of predictability, transparency, costs, and innovation, amongst others. Should these challenges be addressed, this would significantly increase Europe's attractiveness and support the competitiveness of the medical technologies sector which delivers the medical devices and diagnostics that underpin our healthcare systems in Europe and also globally.

50% of manufacturers indicated to discontinue products. Discontinuations had been identified in variability coverage by the European commission in the survey where the most frequent reasons for discontinuation for IVDR/MDR are products low revenue not justifying reapproval, low sales volume, product with low profitability, devices will be replaced by updated/new products and products at the end of their lifecycle (Figure 9& *Figure 17* from Austrian National Public Health Institute, Arete, Civic Consulting, 2024).

5.2.3 Perception of IVDR&MDR:

-58% disagree or completely disagree that the IVDR/MDR regulations aim to enhance safety, transparency, traceability, scrutiny of IVD/MDs in Europe whilst at the same time supporting innovation and protecting the EU market

-42% is not sure that the CE marking system is efficient and 41% disagree or completely disagree that the CE marking system is efficient.

-92% agree or completely agree there is need of a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes.

Similar remarks were concluded from MedTech Europe (2024) in their IVDR&MDR investigation indicate that the following topics require attention: the cost, timelines, predictability, regulatory system improvement to ensure a sustainable system for medical technologies. Their findings highlight the significant uncertainty that manufacturers experience in the timelines and costs associated with IVDR and MDR certification which reflects in deprioritisation of the EU market specially for first launch devices. Also, This gives insight that 50% of the total conformity assessment time is spend by Notified bodies for procedures outside the review phase (pre-review and issue of the certificate) providing the recommendation that there is need of optimization of the pre-submission phase to reduce the total time for conformity assessment by over 30% . Since the pre and post review phases are administrative, they should be efficient and predictable.

-67% disagree or completely disagree and 33% is not sure that the IVDR/MDR promote innovations and they are connecting patients with the latest medical technologies (MedTech Europe, 2024)

-91.7% agree or completely agree that IVDR/MDR need to include an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers (MedTech Europe ,2024)

-(58.4%) disagree or completely disagrees with the affirmation “the governance structure of IVDR/MDR is adequate” 25% was not sure and 16.6 agrees or completely agrees (MedTech Europe, 2024)

- 50 % agree or completely agree that there is need of an accountable Governance Structure consisting of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions" . Whereas 25% is unsure and 8.3 disagrees (MedTech Europe, 2024)

5.3 Needs identified and Next steps

A collaborative approach among medical device stakeholders may improve quality of care, reduce costs, and provide faster access to innovative technologies, with the common objective of improving cardiovascular care and outcomes(Spitzer et al., 2024)

6 Conclusions

It is evident that organizations were prepared to implement IVDR/MDR. Though, they experience different challenges. The cost is high and the implementation of requirements are demanding. Organizations need structured support to achieve higher maturity levels, ensuring compliance with MDR/IVDR article 10 requirements.

The lack of confidence from manufacturers that EU MDR/IVDR in achieving objectives reflects a need for enhanced communication and adjustment of the current legislation. Also, less than 20% of organizations agrees that the CE marking system is efficient indicating a widespread dissatisfaction. Where the neural and negative opinions dominate reflecting systemic issues,

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Appendix 1: Questionnaire designed for this study

RESEARCH TITLE "The impact of the European medical device regulations on Business Management" Dear participant:

We are conducting a survey to study and understand how the European MDR and IVDR regulation has impacted your organization business and management of medical devices companies (structures, processes and investments for example). We invite you to share your experiences and thoughts on this topic with us by answering this questionaire (24 questions). The only criteria for taking the survey are that your organization has experience with European Regulations on medical devices and in vitro diagnostic medical devices. It should take you about 30-45 minutes to answer the questions. The participation in the study is voluntary. You have the right not to participate at all or to withdraw in the middle of the survey. The data will be handled with care and your direct identifiers will be removed from the data once the survey period is over. The questionnaire will be distributed as an internet link and the answers cannot be linked to the participants later. The survey will ask for your willingness to participate in an in- depth interview. All collected data will be anonymised (direct identifiers will be deleted), and the anonymised material will be password-protected and archived on the network drive of the Turku university of Applied Science. The anonymised data will be used for research and teaching purposes and deleted during 2024. (…)If you have any questions about the questionnaire and publication of the results, you can contact me by e-mail: Susan Perez (susankaren.perezgamarra@edu.turkuamk.fi)

I have read the above information about the study. I am participating in the research questionnaire voluntarily. *

- Yes, I have read the above information about the study and will participate in the questionnaire voluntarily.
- No, I decline, I do not want to participate in the research.

1.-Which best describes your position? *

☐senior management
☐ manager
☐ individual contributor
☐ Other

LEARNING ABOUT YOUR ORGANIZATION

2.-What is the company Name and its location?

3.-Aproximate size of your organization ?

☐ <10 employess

☐ 10 to < 50 employees

☐ 50 to < 250 employees

☐ > 250 employees

4.-What is(are) the role(s) of your organization *

☐ legal manufacturer

☐ Distributor

☐ Local representative

☐ Supplier

☐ Other (Specify)

5.-Which best describe the geographical region(s) where your organization has operations?

☐ North America

☐ Europe

☐ Central/South America

☐ Middle East/Africa

☐ Asia Pacific

6.-Which of the following Management Standard (MS) is your organization

certified to

☐ ISO 13485 QMS for medical devices

☐ ISO 9001 general QMS

☐ ISO 14001 environmental health and safety MSS

☐ ISO27001 information security MSS

☐ Medical Device Single Audit Program MDSAP

☐ Not applicable

☐ Other(s).Please specify

7.-Which best describe the region(s) where your medical devices are marketed or where you have regulatory responsibility (answer all that apply)

☐ North America

☐ Europe

☐ Central/South America

☐ Middle East/Africa

☐ Asia Pacific

LEARNING ABOUT YOUR PRODUCTS

SCOPE

8.-Select the regulation(s) under which your products were qualified?

☐ In vitro diagnostic medical device (2017/746)

☐ Medical Device (2017/745))

9.-what are the risk classes of your devices? (select all that apply)

☐ IVD class A

☐ IVD class B

☐ IVD class C

☐ IVD class D

☐ MD class I

☐ MD class IIa

☐ MD class IIb

☐ MD class III

☐ Other (Specify)

LEARNING ABOUT YOUR EXPERIENCE WITH IVDR/MDR

10.-Learning about the influence of the new regulation in your product portafolio

Choose the topics that are relevant to your experience and what kind of challenges you encountered?

☐ Product reclassification,

What has been your experience?

What kind of challenges have you encountered?

☐ Management of resources

What has been your experience?

What kind of challenges have you encountered?

☐ Management of people

What has been your experience?

What kind of challenges have you encountered?

☐ Change in quality procedures

What has been your experience?

What kind of challenges have you encountered?

☐ Technical documentations and submissions

What has been your experience?

What kind of challenges have you encountered?

☐ Update of agreements with economics operators

What has been your experience?

What kind of challenges have you encountered?

☐ Product discontinuation

What has been your experience?

What kind of challenges have you encountered?

☐ Other relevant topic not listed

What has been your experience?

What kind of challenges have you encountered?

11.-What are the gross estimate cost (Euro) for implementing the following IVD or MD regulatory requirements in your organization?

	0-10 000	10 000-50000	50 000-100 000	>100 000
Obligations of manufacturer				
Person responsible for regulatory compliance trainning/services				
Implementation of design and manufacturing requirements				
Information supplied with the device				
implementation of performance evaluation/ performance studies				

safety and clinical performance/ clinical investigation				
Physico-chemical characterization, microbiological, biocompatibility, mechanical, electrical or non-clinical toxicological testing				
Notify body services				
Post-market Surveillance				
Vigilance				

12.- What are the biggest challenges you face while implementing IVDR/MDR? (select all that apply)

☐ regulatory changes in other target markets

☐ new product development

☐ pricing/profitability pressures

☐ funding/capital/credit/financing

☐ increased competition

☐ employee retention/recruiting

☐ changing reimbursement environment

☐ Other

13.-What kind of indicators (key performance indicatios) are you utilizing to determine the impact of IVDR/MDR in your organization?

14.- One bottle neck in the product certification has been the notified bodies (NB) availability, it is known that until the date, there are 11 IVDR and 32 MDR designated notified bodies and several close to be designated. Please, can you describe your experience with your NB?

15.-What kind of improvements would you suggest to your Notified Body?

ASSESSING THE MATURITY OF YOUR RESPONSIBILITIES UNDER MDR/IVDR

16.-IVDR/MDR (Article 10) describe the requirements for Quality Management System. Utilizing the Quality Maturity Assessment Model (ISPE, 2017). What is the maturity level of the following requirements in your organization?

LEVEL	Level 1	Level 2	Level 3	Level 4	Level 5
CHARACTERISTICS	Undefined Uncontrolled Non monitored No evidence	Partially defined Not formally controlled Not formally monitored Person dependent	Defined policy and established processes. Inconsistent application. Inconsistent monitoring.	Defined policy and established processes. Routine application. Routine monitoring.	Defined policy and established processes. Proactive Continuous improvement.

TOPICS	Level 1	Level 2	Level 3	Level 4	Level 5
Strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system					
identification of applicable general safety and performance requirements and exploration of options to address those requirements					
responsibility of the management					
resource management, including selection and control of suppliers and sub-contractors					
risk management					
performance evaluation, including PMPF (post-market performance follow-up)					
product realisation, including planning, design, development, production and service provision					
UDI					
setting-up, implementation and maintenance of a post-market surveillance system					
handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders					
processes for reporting of serious incidents and field safety corrective actions in the context of vigilance					
management of corrective and preventive actions and verification of their effectiveness					
processes for monitoring and measurement of output, data analysis and product improvement.					

LEARNING ABOUT YOUR OPINIONS ON IVDR/MDR

17.-Where would you need further support when implementation regulation?

Please, provide example(s) or what kind of guidelines do you think are still needed?

18.-The IVDR/MDR regulations aim to enhance safety, transparency, traceability, scrutiny of IVD/MDs in Europe whilst at the same time supporting innovation and protecting the EU market. Do you think that this objective will be achieved? Why?

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

19.-Do you agree with the following affirmation "the CE marking system is efficient" Why?

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

20.-Do you agree with the following affirmation "We need a more efficient and resource-effective CE marking system that improves predictability, reduces administrative burden, and adapts to external changes"

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

21.-Do you agree with the following affirmation "the IVDR/MDR promote innovations and they are connecting patients with the latest medical technologies" Why?

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

22.-Do you agree with the following affirmation "IVDR/MDR need to include an innovation principle that swiftly connects the latest medical technologies to European patients and health systems through dedicated assessment pathways and early dialogues with developers"

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

23.-Do you agree with the following affirmation " the governance structure of IVDR/MDR is adequate" Why?

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

24.-Do you agree with the following affirmation "There is need of an accountable Governance Structure consisting of a single, dedicated structure to oversee and manage the regulatory system, including the designation and oversight of Notified Bodies, with the authority to make system-level decisions" Why?

☐ completely agree

☐ agree

☐ not sure

☐ disagree

☐ completely disagree

Please, if you would like to participate in a follow-up interview. Please, provide your contact information. At the end of the study, this information will be deleted according to the GDPR legislation. This information will NOT be linked to your answers, nor showed in the study results.

Names

Email

Appendix 2: EU Medical Device Coordination Group (MDCG) endorsed guidances in accordance with MDR Art. 105 and IVDR Art.99

MDCG guidances are not legally binding, though they present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation (EU commission, latest update Mach, 2025)

Annex XVI products (n=8)	**Reference**	**Title**	**Publication**
	MDCG 2023-6	Guidance on demonstration of equivalence for Annex XVI products - A guide for manufacturers and notified bodies	December 1, 2023
	MDCG 2023-5	Guidance on qualification and classification of Annex XVI products - A guide for manufacturers and notified bodies	December 1, 2023
	Q&A	Q&A on transitional provisions for products without an intended medical purpose covered by annex XVI of the MDR	September 1, 2023
Borderline and Classification (n=6)	**Reference**	**Title**	**Publication**
	Manual on Borderline	Manual on borderline and classification under Regulations (EU) 2017/745 and 2017/746 v3 Background note on the use of the Manual on borderline and classification for medical devices under the Directives.	September 1, 2023
	MDCG 2024-13	Regulatory status of ethylene oxide (EtO) intended for the sterilisation of medical devices	October 1, 2024
	MDCG 2022-5 rev.1	Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices	October 1, 2024
	MDCG 2021-24	Guidance on **classification** of medical devices	October 1, 2021
	Helsinki Procedure	**Helsinki Procedure** for borderline and classification under MDR & IVDR	September 1, 2021
Class I Devices (n=1)	**Reference**	**Title**	**Publication**
	MDCG 2019-15 rev.1	Guidance notes for **manufacturers of class I** medical devices	December 1, 2019
Clinical investigation and evaluation (n=21)	**Reference**	**Title**	**Publication**
	MDCG 2024-15	Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED	November 1, 2024
	MDCG 2024-10	Clinical evaluation of orphan medical devices	June 1, 2024
	MDCG 2024-5	Guidance on the Investigator's Brochure content	April 1, 2024
	MDCG 2024-5 Appendix A	Appendix A of the MDCG 2024-5	April 1, 2024
	MDCG 2024-3	Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices	March 1, 2024
	MDCG 2024-3 Appendix A	Clinical Investigation Plan Synopsis Template	March 1, 2024
	MDCG 2023-7	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access' to data needed to justify claims of equivalence	December 1, 2023
	2023/C 163/06	Commission Guidance on the content and structure of the summary of the clinical investigation report	May 1, 2023
	MDCG 2021-28	**Substantial modification** of clinical investigation under Medical Device Regulation	December 1, 2021

	MDCG 2021-20	Instructions for **generating CIV-ID** for MDR Clinical Investigations	July 1, 2021
	MDCG 2021-8	Clinical investigation **application/notification documents**	May 1, 2021
	MDCG 2021-6 - rev.1	Regulation (EU) 2017/745 – **Questions & Answers** regarding **clinical investigation**	December 1, 2023
	MDCG 2020-13 - Word version	**Clinical evaluation assessment report template**	July 1, 2020
	MDCG 2020-10/1 rev.1	Guidance on **safety reporting** in clinical investigations	October 1, 2022
	MDCG 2020-10/2 rev.1	Appendix: Clinical investigation summary safety report form	October 1, 2022
	MDCG 2020-8	Guidance on **PMCF evaluation report** template	April 1, 2020
	MDCG 2020-7	Guidance on **PMCF plan** template	April 1, 2020
	MDCG 2020-6	Guidance on sufficient **clinical evidence for legacy devices** Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation	April 1, 2020
	MDCG 2020-5	Guidance on **clinical evaluation – Equivalence**	April 1, 2020
	MDCG 2019-9 - rev.1	**Summary of safety and clinical performance**	March 1, 2022
COVID-19 (n=4)	**Reference**	**Title**	**Publication**
	MDCG 2021-21 rev.1	Guidance on **performance evaluation of SARS-CoV-2** in vitro diagnostic medical devices	February 1, 2022
	MDCG 2022-1	**Notice to 3rd country manufacturers** of SARS-CoV-2 in vitro diagnostic medical devices	January 1, 2022
	MDCG 2021-7	Notice to manufacturers and authorised representatives on the **impact of genetic variants on SARS-COV-2** in vitro diagnostic medical devices	May 1, 2021
	MDCG 2021-2	Guidance on state of the art of **COVID-19 rapid antibody tests**	March 1, 2021
Custom-Made Devices (n=1)	**Reference**	**Title**	**Publication**
	MDCG 2021-3	**Questions and Answers** on Custom-Made Devices	March 1, 2021
EUDAMED (n=4)	**Reference**	**Title**	**Publication**
	Gradual roll out of EUDAMED	Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices1	November 1, 2024
	MDCG 2022-12	Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)	July 1, 2022
	MDCG 2021-13 rev.1	**Questions and answers** on obligations and related rules for the **registration** in EUDAMED **of actors other than** manufacturers, authorised representatives and importers subject to the obligations of **Article 31 MDR and Article 28 IVDR**	July 1, 2021
	MDCG 2021-1 rev.1	Guidance on harmonised administrative practices and **alternative** technical **solutions until EUDAMED is fully functional**	May 1, 2021
European Medical Device Nomenclature (EMDN, n=14)	**Reference**	**Title**	**Publication**
	MDCG 2025-3	EMDN Version History	January 1, 2025
	MDCG 2025-2	Summary of EMDN 2024 Submissions and outcome of annual revision	January 1, 2025
	MDCG 2025-1	EMDN Ad hoc procedure	January 1, 2025

	MDCG 2024-2 rev.1	Procedures for the **updates** of the EMDN	January 1, 2025
	MDCG 2021-12 rev.1	**FAQ** on the European Medical Device Nomenclature (**EMDN**)	January 1, 2025
	The EMDN – The nomenclature of use in EUDAMED		January 1, 2020
	The CND nomenclature – Background and general principles		January 1, 2020
	MDCG 2018-2	Future EU medical device nomenclature - Description of requirements	March 1, 2018
Implant cards (n=2)	**Reference**	**Title**	**Publication**
	MDCG 2021-11	Guidance on **Implant Card – Device types**	May 1, 2021
	MDCG 2019-8 v2	Guidance document **implant card** on the application of Article 18 Regulation (EU) 2017/745 on medical devices	March 1, 2020
In-house devices (n=1)	**Reference**	**Title**	**Publication**
	MDCG 2023-1	Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	January 1, 2023
Authorised Representatives, Importers, Distributors (n=3)	**Reference**	**Title**	**Publication**
	MDCG 2021-27 - rev.1	Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	December 1, 2023
	MDCG 2022-16	Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 1, 2022
	MDCG 2021-26	Q&A on **repackaging & relabelling** activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 1, 2021
Article 10a – interruption or discontinuation of supply (n=3)	**Reference**	**Title**	**Publication**
	Q&A rev.1	Q&A Obligation to inform in case of interruption or discontinuation of supply	December 1, 2024
	MDCG 2024-16	Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices	December 1, 2024
	MDCG 2024-16 Annex	Device Identification table	December 1, 2024
In Vitro Diagnostic medical devices (IVD, n=15)	**Reference**	**Title**	**Publication**
	MDCG 2024-11	Guidance on qualification of in vitro diagnostic medical devices	October 1, 2024
	MDCG 2024-4	Safety reporting in performance studies of in vitro diagnostic medical devices under Regulation (EU) 2017/746	April 1, 2024
	MDCG 2024-4 Appendix	Appendix – Performance Study Summary Safety Reporting Form	
	MDCG 2022-9 rev.1	Summary of safety and performance template	April 1, 2024
	MDCG 2020-16 rev.4	Guidance on **Classification Rules** for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	March 1, 2025
	MDCG 2022-20	Substantial modification of performance study under Regulation (EU) 2017/746	December 2022
	MDCG 2022-19	Performance study application/notification documents under Regulation (EU) 2017/746	December 2022
	MDCG 2022-15	Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD	September 2022
	MDCG 2021-22 rev.1	Clarification on "first certification for that type of device" and corresponding procedures to be followed by notified bodies, in context of the **consultation of the expert panel** referred to in Article 48(6) of Regulation (EU) 2017/746	September 2022
	MDCG 2022-10	Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)	May 1, 2022

	MDCG 2022-8	Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC	May 1, 2022
	MDCG 2022-6	Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	May 1, 2022
	MDCG 2022-3 rev.1	Verification of manufactured class D IVDs by notified bodies	December 1, 2024
	MDCG 2022-2	Guidance on general principles of **clinical evidence** for In Vitro Diagnostic medical devices (IVDs)	January 1, 2022
	MDCG 2021-4 rev.1	Application of **transitional provisions** for certification of **class D** in vitro diagnostic medical devices according to Regulation (EU) 2017/746	September 1, 2024
New technologies	**Reference**	**Title**	**Publication**
	MDCG 2023-4	Medical Device Software (MDSW) – Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components	October 1, 2023
	Infographic	Is your **software** a Medical Device?	March 1, 2021
	MDCG 2020-1	Guidance on **clinical evaluation** (MDR) / **Performance evaluation** (IVDR) of medical device software	March 1, 2020
	MDCG 2019-16 rev.1	Guidance on **cybersecurity** for medical devices	July 1, 2020
	MDCG 2019-11	**Qualification and classification of software** - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 1, 2019
Notified bodies (n=37)	**Reference**	**Title**	**Publication**
	MDCG 2024-6	Preliminary re-assessment review (PRAR) form template (MDR)	May 1, 2024
	MDCG 2024-7 rev.1	Preliminary assessment review (PAR) form template (MDR)	January 1, 2025
	MDCG 2021-15/MDCG 2024-7 Annex	Annex to Application Form & PAR Template MDR (List of documents)	
	MDCG 2024-8 rev.1	Preliminary assessment review (PAR) form template (IVDR)	January 1, 2025
	MDCG 2021-16/MDCG 2024-8 Annex	Annex to Application Form & PAR Template IVDR (List of documents)	
	MDCG 2024-9	Preliminary re-assessment review (PRAR) form template (IVDR)	May 1, 2024
	MDCG 2020-3 rev.1	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	September 1, 2023
		Note to the reader: Due to technical issues, please disregard the document displayed from 7 September 2023 until 8 September 2023.	
	MDCG 2023-2	List of Standard Fees	January 1, 2023
	MDCG 2023-2 MDR form		
	MDCG 2023-2 IVDR form		
	MDCG 2022-4 rev.2	Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD	May 1, 2024
	MDCG 2022-17	MDCG position paper on "hybrid audits"	December 1, 2022
	MDCG 2019-6 rev.5	Questions and answers: **Requirements relating to notified bodies**	February 1, 2025
	MDCG 2022-13 rev.1	Designation, re-assessment and notification of conformity assessment bodies and notified bodies	June 1, 2024
	MDCG 2024-12	Corrective and preventive action (CAPA) plan assessment: guidance and templates for conformity assessment bodies, notified bodies, designating authorities, and joint assessment teams	October 1, 2024
	MDCG 2024-12 Annex I Form	Annex I: Template CAPA plan and assessment thereon	

	MDCG 2024-12 Annex II Form	Annex II: Template JAT review of the CAPA and the DA's opinion	
	MDCG 2021-23	Guidance for notified bodies, distributors and importers on **certification activities** in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	August 1, 2021
	MDCG 2021-18	Applied-for scope of **designation and notification of a conformity assessment body** – Regulation (EU) 2017/746 (IVDR)	July 1, 2021
	MDCG 2021-17	Applied-for scope of **designation and notification of a conformity assessment body** – Regulation (EU) 2017/745 (MDR)	July 1, 2021
	MDCG 2021-16 rev.1	**Application form** to be submitted by a conformity assessment body when applying for **designation as notified body** under the in vitro diagnostic devices regulation (**IVDR**)	January 1, 2025
	MDCG 2021-16/MDCG 2024-8 Annex	Annex to Application Form & PAR Template IVDR (List of documents)	
	MDCG 2021-15 rev.1	**Application form** to be submitted by a conformity assessment body when applying for **designation as notified body** under the medical devices regulation (**MDR**)	January 1, 2025
	MDCG 2021-15/MDCG 2024-7 Annex	Annex to Application Form & PAR Template MDR (List of documents)	
	MDCG 2021-14	Explanatory note on **IVDR codes**	July 1, 2021
	MDCG 2020-17	Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body **audits during COVID-19** quarantine orders and travel restrictions"	December 1, 2020
	MDCG 2020-14	Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR)	August 1, 2020
	MDCG 2020-12	Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues	June 1, 2020
	MDCG 2020-11	Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation (EU) 920/2013	May 1, 2020
	MDCG 2020-4	Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions	April 1, 2020
	MDCG 2019-14	Explanatory note on MDR codes	December 1, 2019
	MDCG 2019-13 rev.1	Guidance on sampling of devices for the assessment of the technical documentation	December 1, 2024
	MDCG 2019-12	Designating authority's final assessment form: Key information (EN)	October 1, 2019
	MDCG 2018-8	Guidance on content of the certificates, voluntary certificate transfers	November 1, 2018
	NBOG BPG 2017-2	Best practice guidance on the information required for personnel involved in conformity assessment	February 1, 2018
	NBOG F 2017-8	Review of qualification for the authorisation of personnel (IVDR)	February 1, 2018
	NBOG F 2017-7	Review of qualification for the authorisation of personnel (MDR)	February 1, 2018
Person responsible for regulatory compliance (PRRC, n=1)	**Reference**	**Title**	**Publication**
	MDCG 2019-7 - rev.1	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a '**person responsible for regulatory compliance**' (PRRC)	December 1, 2023
Post-Market Surveillance	**Reference**	**Title**	**Publication**
	MDCG 2024-1	Device Specific Vigilance Guidance (DSVG) Template	January 1, 2024

and Vigilance (PMSV, n=8)	MDCG 2024-1-1	DSVG 01 on Cardiac ablation	January 1, 2024
	MDCG 2024-1-2	DSVG 02 on Coronary stents	January 1, 2024
	MDCG 2024-1-3	DSVG 03 on Cardiac implantable electronic devices (CIEDs)	January 1, 2024
	MDCG 2024-1-4	DSVG 04 on Breast implants	January 1, 2024
	MDCG 2024-1-5	DSVG 05 on Urogynaecological Surgical Mesh Implants used for Pelvic Organ Prolapse repair and Stress Urinary Incontinence	June 1, 2024
	MDCG 2023-3 rev.2	Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746	January 1, 2025
	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745	December 1, 2022
Standards (n=1)	**Reference**	**Title**	**Publication**
	MDCG 2021-5 rev.1	Guidance on **standardisation for medical devices**	July 1, 2024
Unique Device Identifier (UDI, n=14)	**Reference**	**Title**	**Publication**
	MDCG 2024-14	Guidance on the implementation of the Master UDI-DI solution for contact lenses	November 1, 2024
	MDCG 2022-7	Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)	May 1, 2022
	MDCG 2021-19	Guidance note integration of the **UDI** within an organisation's **quality management system**	July 1, 2021
	MDCG 2021-10	The status of Appendixes **E-I of IMDRF N48** under the EU regulatory framework for medical devices	June 1, 2021
	MDCG 2021-09	MDCG Position Paper on the Implementation of **UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers**	May 1, 2021
	MDCG 2018-1 rev.4	Guidance on **basic UDI-DI and changes to UDI-DI**	April 1, 2021
	MDCG 2020-18	MDCG Position Paper on **UDI assignment for Spectacle lenses & Ready readers**	December 1, 2020
	MDCG 2019-2	Guidance on application of **UDI rules to device-part of products** referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017	February 1, 2019
	MDCG 2019-1	MDCG guiding principles for **issuing entities rules on basic UDI-DI**	January 1, 2019
	MDCG 2018-7	Provisional considerations regarding **language issues** associated with the **UDI database**	October 1, 2018
	MDCG 2018-6	Clarifications of **UDI related responsibilities** in relation to **article 16**	October 1, 2018
	MDCG 2018-5	**UDI assignment** to medical device **software**	October 1, 2018
	MDCG 2018-4	Definitions/descriptions and formats of the **UDI core elements for systems or procedure packs**	October 1, 2018
	MDCG 2018-3 rev.1	Guidance on **UDI for systems and procedure packs**	June 1, 2020
Other Topics (n=8)	**Reference**	**Title**	**Publication**
	Q&A	Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860	July 1, 2024
	MDCG 2022-11 - rev.1	MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR and IVDR requirements	November 1, 2023
	Q&A rev.2	Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Extension of the MDR transitional period and removal of the "sell off" periods	July 1, 2024
	MDCG 2022-18 ADD.1	MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate - Addendum 1	June 1, 2023

	MDCG 2022-18	MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate	December 1, 2022
	MDCG 2022-14	Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs	August 1, 2022
	MDCG 2021-25 rev.1	Application of MDR requirements to **"legacy devices"** and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	October 1, 2024
	MDCG 2019-3 rev.1	**Clinical evaluation consultation procedure exemptions** Interpretation of article 54(2)b	April 1, 2020
Other guidance documents (n=4)	**Reference**	**Title**	**Publication**
	MDR/IVDR Language requirements	Overview of language requirements for manufacturers of medical devices for the information and instructions that accompany a device in a specific country	January 1, 2024
	European Medicines Agency (EMA) Guidance	Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)	June 1, 2021
	SCHEER guidelines	Update on the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties	June 1, 2024
	CAMD FAQ	CAMD MDR/IVDR Transition Subgroup: FAQ – MDR Transitional provisions	January 1, 2018