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Regulatory Strategy and Market Access Challenges under EU IVDR 2017/746: A Case Study of Indian IVD Exporters of Rapid Diagnostic Kits

A thesis submitted in partial fulfilment of the requirements for MSc in Medical Device Technology &Business (QQI 9) Innopharma Faculty of Pharmaceutical Sciences
Griffith College Dublin

Submitted By

Adnan Shaikh

Dissertation Supervisor: Caoimhe Reid

August 2025

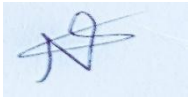
DECLARATION

I, Adnan Shaikh, hereby certify that the dissertation titled *"Regulatory Strategy and Market Access Challenges under EU IVDR 2017/746: A Case Study of Indian IVD Exporters of Rapid Diagnostic Kits,"* submitted in partial requirement for the award of MSc in Medical Device Technology and Business at Griffith College, is the result of my own independent work. I have maintained the highest standards of academic integrity, ensuring that all references to the work, ideas, and contributions of others have been properly acknowledged.

I confirm that this dissertation reflects my original research, analysis, and conclusions, which have been developed through my personal academic efforts. Any external sources, guidance, or support have been appropriately cited, with full recognition given to the intellectual property of others.

I declare that this work has not been submitted previously, in whole or in part, for any other academic degree or professional qualification. Furthermore, I confirm that I have complied with the ethical guidelines and academic regulations of Griffith College throughout the course of this research.

Signed: Adnan Shaikh



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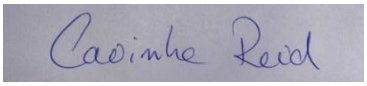

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Acronym table

Acronym	Full Form	Definition / Context of Use
AiMeD	Association of Indian Medical Device Industry	The Indian industry association supports medical device manufacturers.
CAGR	Compound Annual Growth Rate	Overall performance of the variable in the significant period.
CDSCO	Central Drugs Standard Control Organisation (India)	India's regulatory authority for pharmaceuticals and medical devices.
CE Mark	Conformité Européenne	A mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.
CII	Confederation of Indian Industry	Leading industry association in India involved in policy advocacy and industry support.
EUDAMED	European Database on Medical Devices	An EU database that provides transparency and access to information on medical devices, including performance and safety summaries.
EURL	European Union Reference Laboratory	EURLs are laboratories designated by the European Commission to provide independent verification and testing of high-risk In Vitro Diagnostic (IVD) medical devices, particularly Class D devices under EU IVDR 2017/746.
GDPR	General Data Protection Regulation (EU)	European Union regulation on data protection and privacy.
GHTF	Global Harmonisation Task Force	An organisation aimed at harmonising medical device regulation across jurisdictions.
GSPRs	General Safety and Performance Requirements	A set of technical rules that medical devices must meet to be certified as safe and compliant for trade in the European Union.
HIV	Human Immunodeficiency Virus	Referenced in the study for Class D IVD kits (high-risk category).
ISO 13485	International Organization for Standardization 13485	A global standard for QMS specific to medical devices.
IVD	In Vitro Diagnostics	Medical devices are used to perform tests on samples such as blood or tissue outside the human body.
IVDD	In Vitro Diagnostic Directive (98/79/EC)	Previous EU legislation governing IVD devices (replaced by IVDR).

IVDR	In Vitro Diagnostic Regulation (2017/746)	Current EU regulation establishes stricter requirements for IVD devices, including risk-based classification and CE marking.
MDCG	Medical Device Coordination Group	An EU body guiding the implementation of medical device regulations.
NB	Notified Body	Independent organisations designated by EU member states to assess the conformity of IVD devices under the IVDR.
PER	Performance Evaluation Report	A technical document required under IVDR demonstrating the scientific, analytical, and clinical performance of a device.
PMPF	Post-Market Performance Follow-up	Specific activities to collect and analyse data to confirm the continued performance and safety of a device.
PMS	Post-Market Surveillance	Ongoing monitoring of the safety and performance of a device after it has been released on the market.
QMS	Quality Management System	A structured system of procedures and processes covering all aspects of design, manufacture, and distribution to ensure product quality, typically ISO 13485 certified.
SSCP	Summary of Safety and Clinical Performance	Document is compulsory under the EU MDR for implantable and Class III medical devices approval.
SME	Small and Medium-sized Enterprise	Companies with limited resources often face greater challenges in complying with IVDR due to cost and expertise constraints.
UDI	Unique Device Identification	A system used to mark and identify medical devices through distribution and use, enhancing traceability.

Abstract

The introduction of the In Vitro Diagnostic Regulation (IVDR) is one of the most significant regulatory shifts, affecting the European diagnostics industry. The regulation aims to increase patient safety, reliability, and transparency, but with this has come very strict demands that have overwhelmed the preparedness of many organisations. Nevertheless, there is a scarcity of empirical studies focused on how firms manage the new demands and address them, especially in terms of resource allocation, impediments to compliance, and adaptation to strategic change.

Therefore, this research was conducted to critically reflect upon the preparation of organisations to comply with the IVDR and their policy margins, as well as the policy implications of the regulation. It used mixed methods, which included both quantitative survey responses as well as qualitative interviews, analysed using qualitative content analysis. This integration offered not only statistical data, but also a deep contextual knowledge of the industry experiences.

The results indicated that there are three main themes: regulatory barriers focused on Notified Body scarcity and vague guidance; organisational preparedness that linked to resource endowment, re-strategising QMS, and digitalisation; and perceived benefits linked to greater market credibility, quality assurance, and patient confidence. As per analysis, it was identified that even though larger firms were more resilient, SMEs were over-represented in being burdened, which causes the problem of innovation and diversity in the competitive market.

Furthermore, this research recommended that increasing the capacity of Notified Bodies, harmonising the regulatory guidelines as well, and implementing SME-specific compliance facilitating measures to reduce regulatory burdens. They also include proactive organisational strategies such as the use of digital traceability tools and the rationalisation of portfolios that can be addressed by organisations in order to enhance preparedness. Using empirical findings and practical recommendations, this study can make a contribution both to the understanding of the academic field and the practice of regulation, with foundations for future additional research and adaptation to the industry.

Keywords: Regulatory Strategy, Market Access Challenges, EU IVDR 2017/746, Indian IVD Exporters, Rapid Diagnostic Kits

Chapter 1
Introduction

Chapter 1: Introduction

1.1 Background

At the current time, the In Vitro Diagnostic (IVD) industry is a vital component of any healthcare system in the international market, as it allows prompt diagnosis and control of illnesses. Today, the world IVD market is valued at about USD 92.03 billion, and is expected to grow to USD 108.66 billion by 2030 at a compound annual growth rate (CAGR) of 3.38 % (Statista, 2025a). Due to changes in technology and safety demands, in 2022, the European Union (EU) substituted the original In Vitro Diagnostics Directive (IVDD 98/79/EC) with the more comprehensive In Vitro Diagnostic Regulation (IVDR 2017/746) (EUR, 2017). Furthermore, in 2022, the In Vitro Diagnostic Regulation (IVDR 2017/746) came into effect, which focuses on different compliance and is achieved by risk classification (Cobbaert *et al.*, 2022).

The regulation requires performance evaluation reports (PERs), post-market performance follow-up (PMPF), introduction of the unique device identification (UDI) system and also involves the risk-based classification of devices (Classes A to D) along with compliance with general safety and performance requirements (GSPRs) (Valla *et al.*, 2021). The products associated with a moderate risk, like pregnancy test kits (Class B), to severe risk products like HIV diagnostic kits (Class D) are under an increased level of scrutiny about clinical data and the requirement of mandatory Notified Body (NB) participation (Valla *et al.*, 2021). Furthermore, these changes increase the cost and time necessary to obtain the Conformité Européenne (CE) mark in the EU. For manufacturers in non-European countries, it is difficult to navigate the new regulatory landscape (EUROPA, 2025).

These changes in regulations have a direct consequence on India. India is one of the largest exporters of generic drugs and low-cost diagnostic equipment in the world today. The Indian medical device market was worth US$11 billion in 2022 and is growing at a 16.4% CAGR (IBEF, 2025). The Indian market is still in the process of import-dependency, where 70-80% of medical devices are imported (IBEF, 2025), although India has already widened its regulatory landscape by extending the number of NBs registered with the Central Drug Standard Control (CDSCO) from 09 to 13 in 2023 (CDSCO, 2023).

There are several barriers that the Indian IVD industry has to contend with to penetrate the EU market with IVDR. One is that designated NBs are still in short supply in the EU; by the

end of 2024, the number of NBs designated to perform IVDR conformity assessment stood at only 18 bodies, and they had long queues and little capacity to serve non-EU-based clients (EUROPEAN COMMISSION, 2025b). Furthermore, Indian companies, particularly small to medium enterprises (SMEs), are unable to produce detailed technical documentation and achieve EU clinical performance evidence because they do not have accredited EU testing partners and in-house capabilities (DOP, 2023a). Moreover, post-market surveillance (PMS) and traceability systems that should be implemented according to the IVDR are also challenging to set up, considering the underdeveloped infrastructures (Hallersten *et al.*, 2023). Therefore, the EU IVDR has resulted in a special regulatory environment that requires Indian IVD exporters to make robust organisational, technical, and strategic modifications. Their preparedness and adjustments to overcome obstacles are important to sustained access in the European market.

1.2 Research Problem

The EU IVDR 2017/746 implements major regulatory challenges to manufacturers of diagnostic devices, particularly non-EU-based manufacturers (Lubbers *et al.*, 2021). Indian IVD exporters, which mostly offer cost-effective rapid diagnostic kits, including HIV and pregnancy tests, to international markets, are increasingly subjected to changes in conformity assessment procedures, greater dependence on NBs, and broadened documentation requirements (Kohli and Agnihotri, 2022). India is increasing its presence in the medical device industry globally, but most of the small and medium Indian IVD developers do not have the resources, technical infrastructure, and regulatory understanding to meet the complete requirements of IVDR (Singh and Abrol, 2017). Moreover, the current studies focus on the theoretical annotations of IVDR reforms. There is very little empirical data that quantifies how Indian manufacturers are dealing with these reforms in practice. Specifically, there is not much information available regarding how their business strategies, altered operational changes, investment trends and compliance schedules. However, there is less empirical data regarding the actual reaction to these reforms by Indian manufacturers, both in terms of strategy and operation. The main issues are related to delays of CE certification, insufficient access to NBs, issues with updating technical files, as well as the insufficient implementation of post-market surveillance systems (Baines *et al.*, 2023). In addition, due to transition deadlines to the IVDR, it is important to evaluate the extent of preparedness of the

Indian exporter, as well as the barriers that lie specifically in their path (Propharma, 2022). It is also essential to understand these challenges to improve diagnostic supply chains in the EU, ensuring a steady flow of supplies from these countries to producers and maintaining continuity of supply to Indian manufacturers.

1.3 Research Aim, Objectives, and Questions

1.3.1 Research Aim

This study aims to qualitatively evaluate the strategic adaptations of Indian IVD manufacturers, specifically in the domains of regulatory compliance and market access in response to the EU IVDR 2017/746, with a focus on Class D HIV kits and Class B pregnancy kits.

1.3.2 Research Objectives

To achieve the research aim, a number of objectives have been identified. These objectives focus on the analysis of regulatory, strategic and operational characteristics connected with CE marking and access to the EU market.

- To investigate the organisational and strategic changes implemented by Indian IVD manufacturers to comply with EU IVDR 2017/746, particularly in regulatory affairs and quality assurance.
- To identify the key compliance challenges—such as access to NBs, resource limitations, and PMS—encountered during the IVDR transition.
- To explore how Indian manufacturers are updating technical documentation, including PERs and clinical evidence, to align with IVDR.
- To assess the impact of IVDR on CE marking timelines and overall EU market accessibility for Indian IVD exporters.
- To recommend practical strategies for improving the IVDR compliance readiness of Indian IVD kit manufacturers based on research findings.

1.3.3 Research Questions

The research questions below have been formulated to guide the study significantly, address the research objectives and help to attain the research aim.

- What are the organisational and strategic changes implemented by Indian IVD manufacturers to comply with EU IVDR 2017/746, particularly in regulatory affairs and quality assurance?
- How do key compliance challenges, such as access to Notified Bodies, resource limitations, and PMS, encountered during the IVDR transition
- How are Indian manufacturers updating technical documentation, including PERs and clinical evidence, to align with IVDR?
- What is the impact of IVDR on CE marking timelines and overall EU market accessibility for Indian IVD exporters?

1.4 Research Rationale

The commencement of the EU in Vitro Diagnostic Regulation (IVDR 2017/746) is a profound step in the direction of the regulation of diagnostic devices in Europe. This regulation has increased the need for technical documentation, performance evaluation, and post-market surveillance, especially for companies producing high-risk Class D and Class B diagnostic kits (Badnjević *et al.*, 2022). Furthermore, in the export market, Indian IVD exporters are a major source of low-priced diagnostic kits to global markets and are now subjected to serious impediments in their business capacities to continue in the EU markets. Although these changes are quite significant and there is no substantial empirical evidence as to how in-country companies are restructuring their internal strategies, documentation practices, and regulations to comply with IVDR requirements (Kahles *et al.*, 2023).

To eliminate that gap, this research will be fundamental as it proposes to examine the key responses of Indian IVD manufacturers both structurally and strategically, particularly towards CE marking, accessibility to the NBs, and compliance preparedness. Furthermore, this research is of utmost importance because there is a need to gauge practical difficulties faced by exporters and arrive at viable techniques for improving their compliance. Furthermore, due to the complicated nature of the IVDR and its non-concurrent application, this research will deliver current observations as to how Indian companies can streamline their assimilation of regulatory changes across Europe and maintain a competitive edge in the global market.

1.5 Research Structure

The dissertation is structured with five chapters that focus on the examination of regulatory and market access issues associated with the Indian exporters of IVD rapid test kits in the EU in Vitro Diagnostic Regulation (EU IVDR 2017/746). ***Chapter 1*** presents the background, purpose, objectives, and significance of the research. It frames the main objectives and identifies the limitations of the research, and provides the broader scope of regulatory compliance and international trade in the field of medical devices. Furthermore, the critical literature review in ***Chapter 2*** summarises the recent findings in the literature regarding the health technology regulatory environment in all parts of the world, especially the impacts of the EU IVDR on non-EU manufacturers. ***Chapter 3*** defines the way that the study is going to be conducted, including the philosophical position, method of research design, and data collection and data analysis. In the ***fourth chapter***, the results and discussion will be presented. This section analyses the first-hand data that will be gathered related to the field of regulatory affairs and quality assurance at Indian IVD businesses. ***Chapter 5*** presents a conclusion of the dissertation with a review of the main findings regarding the research objectives. It offers advisory and scholarly suggestions towards making the Indian IVD exporters ready for compliance with IVDR 2017/746.

Chapter 2
Literature Review

Chapter 2: Literature Review

2.1 Introduction

This chapter critically reviews the literature that focuses on the regulatory changes that come with the EU IVDR 2017/746 and focuses on the implications of change on the global IVD manufacturers, with particular consideration for the Indian exporters. It addresses some of the main themes, such as regulatory reforms, strategic organisational adaptations, requirements of technical documentation and problems of market access. The review pinpoints how the non-EU manufacturers that are represented mainly by SMEs are going through the changes and points out the lack of empirical evidence as to the readiness of the Indian enterprises. The analysis of these themes gives the conceptual and contextual background of the main research that was carried out in this study.

During the analysis, it was identified that most of the literature concerning the realisation of the EU IVDR 2017/746 and its overall regulatory consequences is growing. However, there are still several gaps, especially those that reflect on the effects it will have on non-EU producers. The available literature has mainly involved European stakeholders, large multinational enterprises and hypothetical explanations of regulating change. However, a low number of empirical studies can specifically show how the Indian exporters of IVD are coping with IVDR requirements. In addition, limited literature exists on the structural or procedural modifications that the SMEs have gone through in India to solve the problem of CE marking, preparing technical documentation, or involving the NBs.

In addition, data on the field readiness of the Indian companies, their level of accessibility to the verified laboratories, or the financial and paper-related obstacles that they encounter during the process of conformity assessment are not present in published work. Also, there is a lack of analysis at a case level, such as firm-level regulatory approaches, use of external consultancy and decision-making practices in case of withdrawals or prioritisation under IVDR. Moreover, these factors provide the need to conduct research based on the personal experiences of the regulatory experts working in the Indian IVD sector.

2.2 The Evolution of IVD Regulation in Europe

IVD devices represent an important part of modern healthcare that allows early diagnosis of diseases, monitoring of the patient's condition or disease progression, and shaping clinical decisions. The devices have a big implication on the outcomes of patients and help to regulate them closely, which is necessary to achieve accuracy, safety, and reliability. The first regulation that applied to the EU, IVDD 98/79/EC, was introduced in 1998 and was the first step in the harmonisation of IVD standards within Europe. But it also possessed significant weaknesses, along with the number of required external reviews of the in vitro diagnostic devices and the requirements of the clinical performance being relatively low.

To fill these gaps, the In Vitro Diagnostic Regulation (IVDR) 2017/746 has been entered, encouraging additional levels of control by adopting risk-based categories, commercial PERs requirement, and PMS intensification (Valla *et al.*, 2021). Figure 1 illustrates the transition from IVDD to IVDR, showing key milestones, overlapping grace periods, and phased compliance deadlines, alongside related MDR/AIMDD frameworks and certificate validity timelines (Lek, 2019).

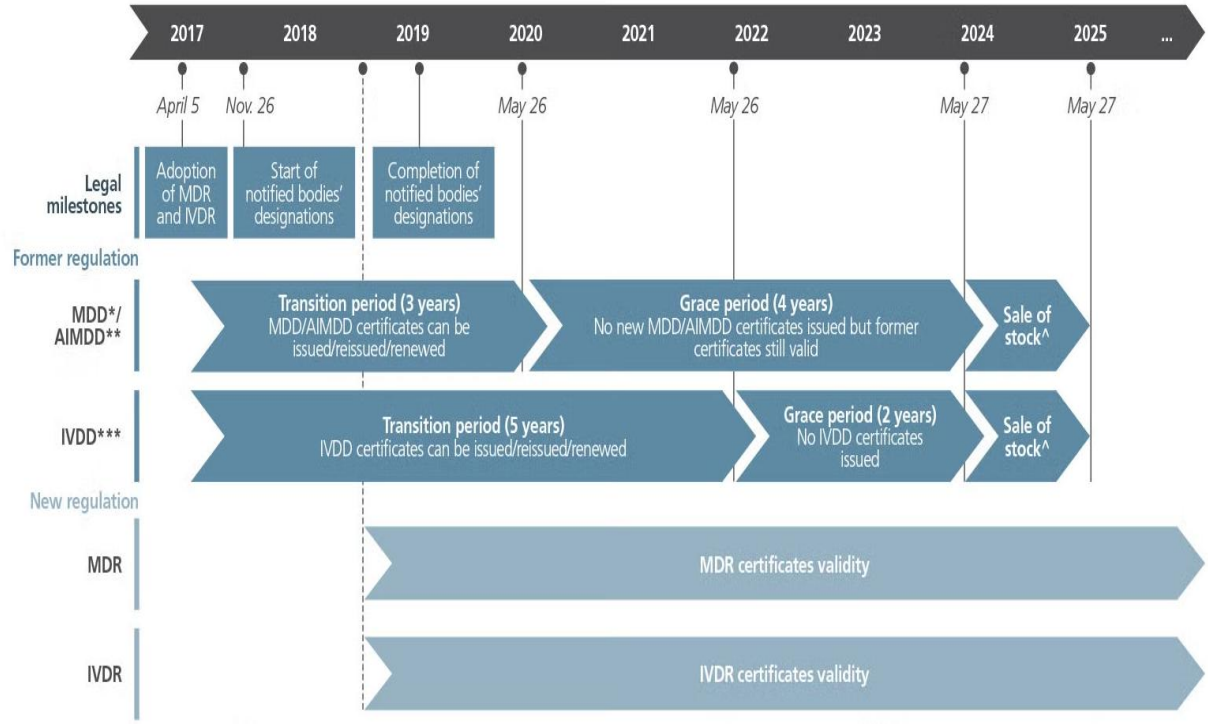

Figure 1: European market and regulatory change

Source: (Lek, 2019)

The basis of the IVDR is the NBs, which are independent organisations charged with the role of device conformity assessment, particularly for Class B, C, and D devices. They also appraise technical documentation, audit manufacturers, and check that EU safety standards are met (Valla *et al.*, 2021). Therefore, IVDR is one more step for the world aimed at better patient safety and transparency in diagnostics.

2.3 Impact of Global Regulatory Reforms in the IVD Industry

2.3.1 Transition from IVDD to IVDR

In Vitro Diagnostic Regulation (IVDR 2017/746) of the EU was adopted in 2017 and became applicable in May 2022, to take into account the current changes in the field of in vitro diagnostic medical devices. (Hermans *et al.*, 2022), and provides closure of some gaps, replacing the previously existing In Vitro Diagnostic Directive (IVDD 98/79/EC) implemented in 1998. Table 1 outlines the key differences between IVDD and IVDR.

Table 1: Key Differences between IVDD and IVDR

Feature	IVDD (98/79/EC)	IVDR (2017/746)
Date of Implementation	1998	2017 transitional period until 2027 (final deadline, depending on risk class).
Classification System	List-based (Annex II + Self-test)	Risk-based (Classes A–D)
Notified Body Involvement	10% of IVDs required NB review	90% of IVDs now require NB review
Clinical Evidence	Not consistently required	Mandatory performance evaluation (Scientific, Analytical, Clinical)
Post-Market Surveillance	Minimal requirements	Extensive PMS and vigilance obligations
Transparency	Limited public access to data	EUDAMED registration, increased transparency
Companion Diagnostics	Not regulated	Specifically addressed with clear requirements
CE Marking Route	Mostly via self-declaration	The majority via NB assessment
Scope	Narrower, limited test types	Broader, covering a wider range of IVDs

The IVDD had permitted 90% of IVD products to be self-certified by manufacturers, which shows that they could be put into circulation without external scrutiny. On the contrary, the IVDR proposes a rigorous system of regulation, and approximately 90% of devices must go through a conformity assessment procedure with an NB (Cobbaert *et al.*, 2022). It took effect

in 2022, with the implementation horizon extending to 2027 by category of devices as per Figure 1. Among the most crucial alterations is the proposal of the risk-based classification system (Classes A to D), based on the level of risk (Baumgartner *et al.*, 2023).

2.3.2 Core Regulatory Requirements under IVDR

In Vitro Diagnostic Regulation (IVDR 2017/746) presents an in-depth and harmonised body of regulatory requirements, which considerably increases the level of conformity assessment, technical documentation, and PMS within the EU (Hallersten *et al.*, 2023). In contrast to its predecessor, the IVDD, the IVDR will lead to the manufacturers being involved in a far more comprehensive process of the review of device functionality and safety (Spitzenberger *et al.*, 2022). The primary element for approval introduced under the IVDR framework is the requirement to prepare PERs for all diagnostic devices. Furthermore, the reports, such as scientific validity reports, analytical performance reports, and clinical performance studies, show how the diagnostic device is used, especially on products of higher risk that fall under Classes B to D (Kohli and Agnihotri, 2022). Figure 2 outlines the EU IVDR compliance process for IVDs, covering classification, QMS implementation, technical documentation, authorised representative appointment, EUDAMED registration, Notified Body audit, CE marking, and ongoing post-market compliance through audits and batch testing.

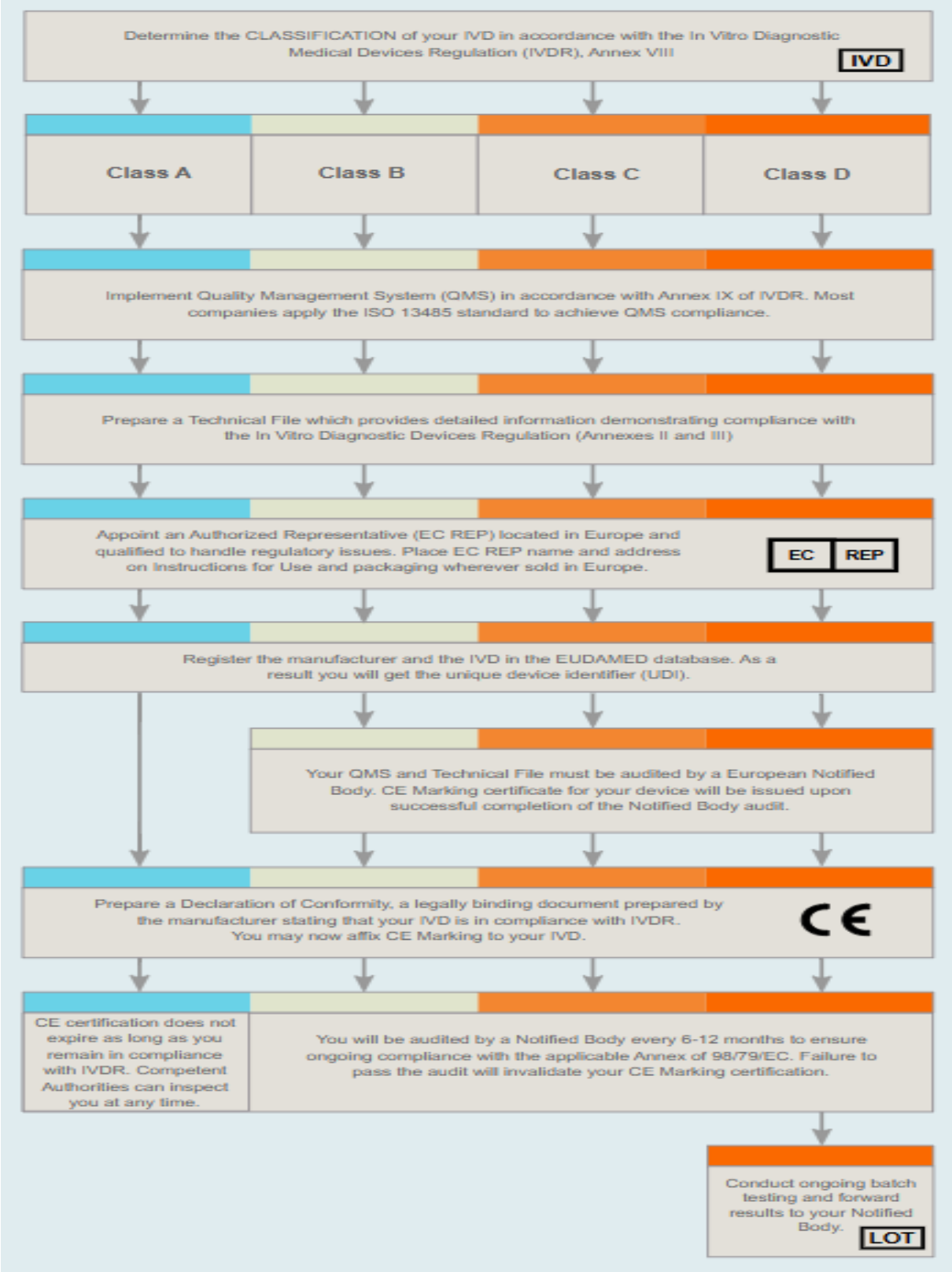

Figure 2: Europe's IVD regulatory approval process

Source: (MDRC, 2025)

The proper regulation of medical devices must include a guarantee of efficient product recall systems in situations when a defective or unsafe device is detected after being placed on the market (FDA, 2025). The timely recall can prevent patients from injuries, maintain the people's trust in the healthcare system and prevent the violation of its integrity. In this regard, one of the major requirements that is being stated with the introduction of IVDR is the use of the UDI system. The UDI is used to trace every IVD product along the supply chain, and this feature allows a quick identification of the affected batches (EUROPA, 2022). Table 2 outlines UDI application across the IVD product lifecycle, detailing UDI carrier examples, encoded information, and traceability purposes from raw material sourcing to post-market surveillance for quality, safety, and recall management.

Table 2: UDI Application and Traceability in an IVD Product Lifecycle

Stage in Supply Chain	UDI Carrier Example	Information Contained in UDI	Purpose of Traceability at This Stage
Raw Material Procurement	Barcode on bulk material label	Supplier ID, batch number, production date	Tracks the origin of raw materials, ensures quality source verification
Manufacturing	QR code on device foil packaging	Device Identifier (DI), lot number, expiry date	Links the device to the production batch and testing records
Secondary Packaging	Barcode on the retail box	DI, lot number, manufacturing site	Enables traceability at the retail level, supports recalls
Tertiary Packaging	Barcode/RFID on shipping carton	DI, quantity, batch code	Allows tracking in bulk shipments and warehouse management
Palletization & Export	Pallet label with barcode/RFID	DI, destination, shipment date	Tracks bulk logistics and export records
Distribution & Retail	Barcode scan at the pharmacy or hospital	DI, batch, expiry date	Verifies authenticity before dispensing to the end user
Post-Market Surveillance	Scanned UDI in EUDAMED	DI, performance data, adverse events	Monitors product safety, supports recall if needed

This traceability also helps in incident reporting, inventory management and better protection for patients. Therefore, the IVDR will introduce greater transparency as manufacturers will be required to develop and keep a Summary of Safety and Clinical Performance (SSCP) document. This summary is publicly available on the European Database on Medical Devices (EUDAMED) and can assist a clinician and a patient to make rational decisions based on its performance and clinical evidence (EUROPA, 2022).

These requirements are all incorporated into a wider mandate, which is the need to adopt the Quality Management System (QMS) that meets the standards like ISO 13485:2016 (Sharma and Luthra, 2023). The QMS can show the control of the design process, production process,

clinical evaluation process and complaint process. To a vast majority of companies, including non-EU-based SMEs, organising internal procedures and policies to comply with such frameworks is a significant challenge in terms of both operational effort and financial expense (MedTech Europe, 2025).

2.3.3 Global Impact of IVDR on Non-EU Manufacturers

At the current time, the effect of IVDR is not limited to the EU. Any country that wants to export to Europe should be adapted to such standards or be denied access (Kahles *et al.*, 2023). This has placed huge barriers on manufacturers outside the EU, especially those in emerging economies such as India. Furthermore, in the case of EU-certified partners, they have to produce the necessary clinical evidence and documents to overcome the barriers. India expanded its total number of Indian standards-based Notified Bodies authorised by CDSCO to 13 in 2023 (CDSCO, 2023). But on the other hand, the deficiencies in technical competence and limitations in access to NB imply that the majority of Indian companies do not find it easy to achieve CE marking in the new regime (Kanti *et al.*, 2022). Irregular documentation and delay in performance confirmation are also frequent bottlenecks, and they further reduce the existing small Indian presence in the high-value EU-based IVD market (CDSCO, 2024).

2.3.4 Compliance Costs and Strategic Pressure

IVDR is much more costly to comply with compared to IVDD. It is estimated that the cost of complying with IVDR will be five to tenfold more than complying with IVDD, especially in the case of Class B and D devices (Bank *et al.*, 2021). This is a heavy cost, especially to the SMEs, where most are contemplating abandoning the EU as a market because of low returns on investment in complying with regulations. In fact, due to the scope of changes, most Manufacturers find it necessary to conduct an internal reconstruction process: recruit regulatory experts, revise QMSs (ISO 13485), and partner with EU-based organisations just to ensure regulatory compliance (Wu *et al.*, 2025). The IVDR brings one of the greatest regulatory regimes worldwide that completely changes the regulatory playing field for manufacturers of IVDs (EC, 2025). On the one hand, it contributes to safety and standardisation, but on the other hand, it is expensive in terms of regulations, and economically it puts a burden on the exporters of the emerging market countries like India

(Christen *et al.*, 2022). In the case of these companies, IVDR adaptation is not merely a matter of compliance but a matter of strategy, which defines their future in the EU market.

2.4 Analysis of EU IVDR Requirements and Strategic Implications

2.4.1 Introduction to the IVDR Framework

The EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) can be considered as an essential change to the EU diagnostic market regulation (EUR, 2017). Starting its application in 2022, it superseded regulations within the In Vitro Diagnostic Directive (IVDD 98/79/EC) and replaced it with a more sophisticated, transparent, and risk-based model of IVD devices regulation stated in Figure 3 (Valla *et al.*, 2021). The IVDR is intended to both promote patient safety and strengthen traceability, as well as to allow high-quality diagnostic devices to enter and stay in the EU market.

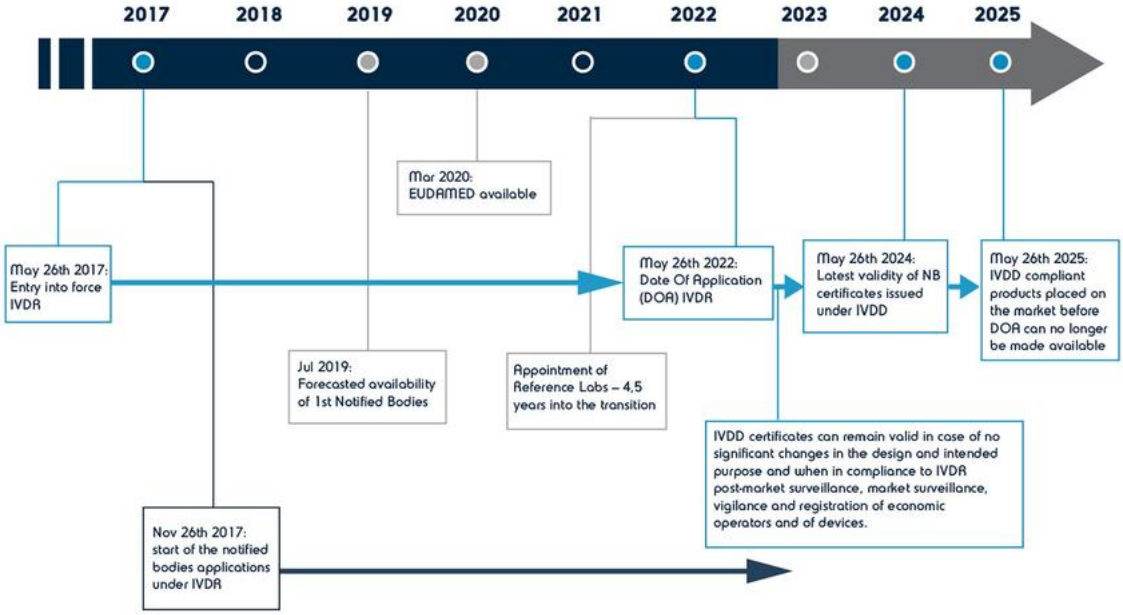

Figure 3: Implementation of IVDR Regulation

Source: (Valla *et al.*, 2021)

IVDR puts Europe in line with the Global Harmonisation Task Force (GHTF) classification system and implies new procedures of conformity assessment that will have a great impact on manufacturers all over the globe (Hallersten *et al.*, 2023). It features transitional rules that offer the advantage of implementing the requirements in phases depending on device type, and ends with final compliance dates extending to May 2027 on the lower-risk devices (Figure 4). Unless the companies manage to certify against the IVDR requirements by the given transitional timelines, they face a risk of losing market authorisation in the EU (Valla *et al.*, 2021). In addition, non-compliant devices will not be allowed to remain on the EU market or be available to end-users once the transition period is over. The European Commission states that after the deadline, manufacturers will not be able to sell the product without a valid CE certificate issued under IVDR, so they can either withdraw or consider repurposing (Valla *et al.*, 2021). Therefore, this enforcement of regulation is aimed at removing all of the devices which do not follow the new and increased level of safety and performance standards.

Figure 4: Timeline of IVDR Transitional

(Source: TÜV SÜD, 2025)

2.4.2 Risk-Based Classification and CE Marking Pathways

One of the most significant changes brought by the IVDR is the risk-based classification. IVDR is categorised into four classes: Class A (low risk), Class B (moderate risk), Class C (high risk), and Class D (highest risk) in line with the intended purpose of in vitro diagnostic devices, as outlined in Figure 5 and Table 3 below. It is a particular classification system referring to IVDs and distinct from other medical devices regulated under Medical Device Regulations 2017/745, which are categorised as Class I, II, and III (Propharma, 2022). Furthermore, the HIV diagnostic kits belong to Class D, and the pregnancy test kits belong to Class B stated in Figure 5. Rapid diagnostic tests, including pregnancy and HIV kits, play an important role in decision-making in medicine and community health (Propharma, 2022). As pregnancy test kits are categorised in Class B, they are moderately dangerous because a false result can lead to emotional disturbances or a failure to start prenatal care in time, but not cause substantial health risks.

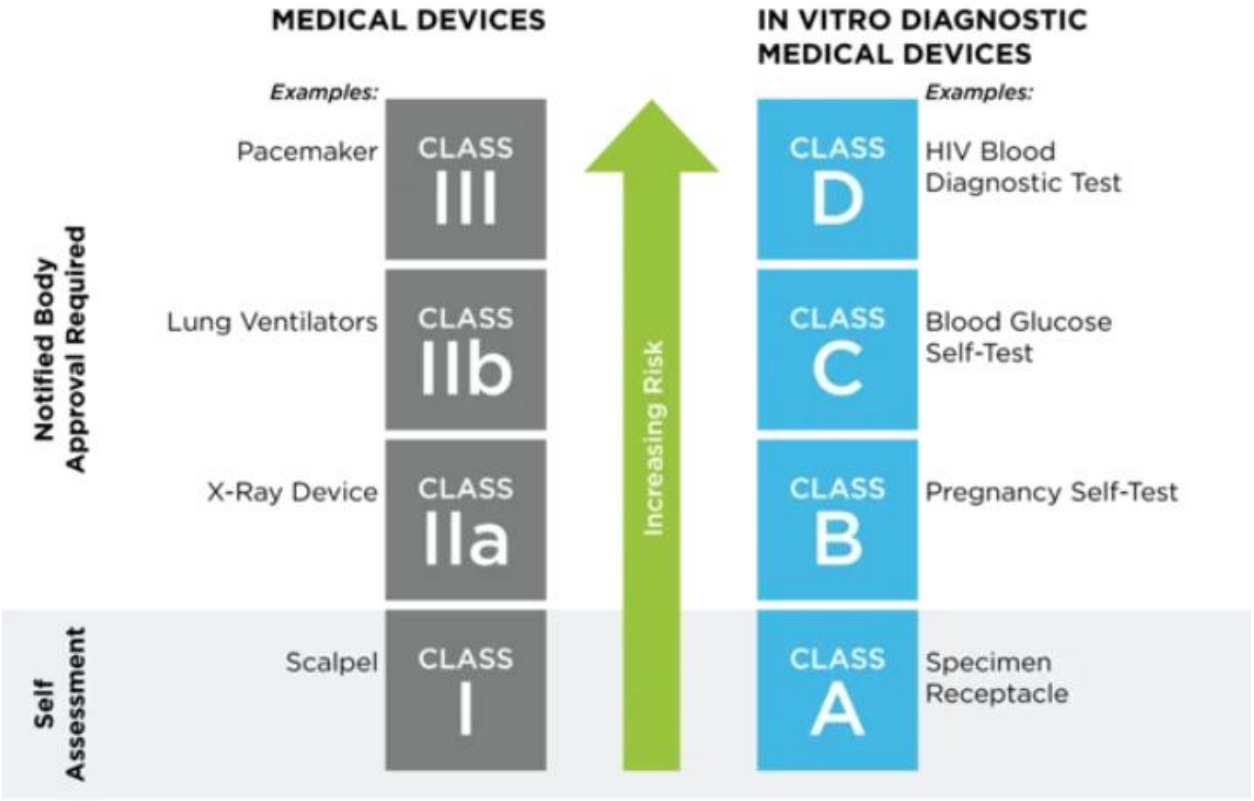

Figure 5: IVDR Classification

Source: (Propharma, 2022)

Conversely, HIV test kits that fall in the Class D category represent the highest risk category and pose false negative results, potentially missing the opportunity for early treatment and possibly unintentionally spreading the disease to others. Table 3 shows the different IVD classes and their corresponding risks. This comparison demonstrates the value of proper performance of rapid diagnostics and the regulatory control of high-impact devices by IVDR.

Table 3: Class and corresponding risk

Class	Risk Level	Description	Devices
A	Low	Minimal risk to the individual and public health.	Laboratory instruments, buffers
B	Moderate	Moderate risk; an incorrect result may cause a delay in diagnosis.	Pregnancy test kits
C	High	High individual risk; incorrect results may lead to serious medical consequences.	Blood glucose meters
D	Highest	High public health risk; life-threatening consequences if the result is incorrect.	HIV diagnostic kits, blood screening tests

The basis of this classification system is to define the conformity assessment route that the manufacturer should undertake to obtain the CE mark required to process the sale of any IVD product anywhere in the EU (Baumgartner *et al.*, 2023). Acquisition of CE marking will show that an IVD device conforms to all the safety requirements, health, and performance systems as required by the EU, and is legally sold as stated in Figure 6. This procedure includes risk categorisation, choice of the conformity pathway, compilation of the technical documentation and certification by an NB in Class B, C and D devices.

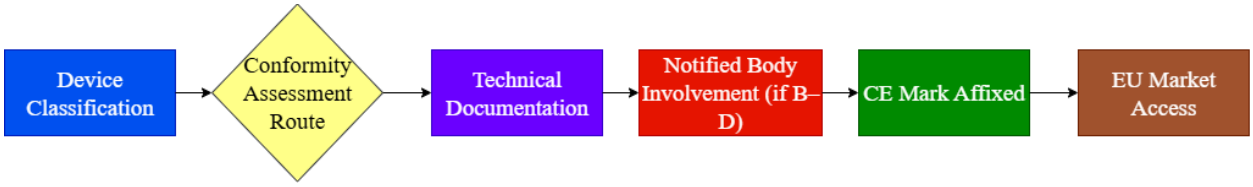

Figure 6: Steps in the CE Marking Process for IVD Devices under IVDR

Source - (Hallersten *et al.*, 2023)

The increase in demand has posed a big burden on the small number of designated NBs. Due to this, it becomes one of the biggest bottlenecks during the CE marking process and directly increases delays in conformity assessment, timelines of certifications and impacts product entry into the market (Hallersten *et al.*, 2023). The majority of manufacturers are now required to have their products reviewed externally instead of their self-declaration of

conformity (Hallersten *et al.*, 2023). Table 4 below provides the detailed information related to the role and importance of NBs under IVDR.

Table 4: Role and Importance of Notified Bodies (NBs) under IVDR

Aspect	Description
Definition	Notified Bodies (NBs) are independent, third-party organisations designated by EU member states and approved by the European Commission.
Purpose	Their primary role is to assess the conformity of in vitro diagnostic (IVD) devices before they are allowed on the EU market.
Regulatory Authority	Operate under Regulation (EU) 2017/746 (IVDR) and are subject to regular oversight by national competent authorities and the European Commission.
When NBs Required	Required for Class B, C, and D IVDs (moderate to highest risk). Class A (low risk) devices do not require NB involvement and may be self-certified, except for sterile devices.
Key Responsibilities	Assess Technical Documentation to verify safety and performance data Audit Quality Management Systems (QMS) Oversee Performance Evaluation, including clinical evidence, Scientific, and analytical validity. Monitor Post-Market Surveillance (PMS) and vigilance obligations.
Outcome	Upon successful assessment, the NB issues a CE Certificate, enabling the manufacturer to affix the CE mark and legally place the device on the EU market.
Significance	Ensure rigorous regulatory compliance for public health protection Act as regulatory gatekeepers to reduce the risk of unsafe or ineffective devices Help harmonise market standards across EU/EEA countries
Challenges	The limited number of designated NBs under IVDR has led to bottlenecks Increased workload due to a rise in devices requiring NB review Potential delays in product approvals and market access

This shift is directed to improve the safety of the type of devices and provide effective oversight, but it also increases the regulatory burden and cost of compliance on the part of the manufacturer (Hallersten *et al.*, 2023).

2.4.3 Technical Documentation and Performance Evaluation

IVDR requires more technical documentation that must contain a complete description of the device, its manufacturing process, safety and performance information, labelling and instructions for use. One of the main conditions is the formation of a PER, which includes a scientific, analytical and clinical path aspect and helps to evaluate the performance of the device against the criteria (Vasey *et al.*, 2022). These three aspects (scientific, analytical and

clinical path) help to determine whether any device is safe, reliable and compatible with its intended uses (Vasey *et al.*, 2022).

The IVDR adds extra oversight to Class D, high-risk products, which include devices that diagnose transmissible agents such as HIV or Hepatitis (Valla *et al.*, 2021). These products must be independently verified by an EU-designated reference Laboratory (EURL), which tests the analytical and clinical performance of the product, compliance with Common Specifications (CS), and accuracy of the test (EUROPEAN COMMISSION, 2025a). This ensures that the devices are highly performing and that they are safe in line with the standards necessary in order to be CE marked and to enter the European Union market (EUR, 2017).

The Performance Evaluation Report (PER) may include data from NABL-accredited Indian laboratories (ISO 15189 / ISO 17025), as officially recognised by CDSCO (NABL, 2025). However, for CE marking, especially for Class D IVDs like HIV test kits, the EU Notified Body cannot rely solely on this data, so independent verification by an EURL is still required (EUROPEAN COMMISSION, 2025a). Figure 7 displays a flow chart of CE marking steps and activities of a Class D IVD within the scope of the IVDR, including performance evaluation, technical documentation, verification by an EURL, the conformity assessment, and achievement of EU market access.

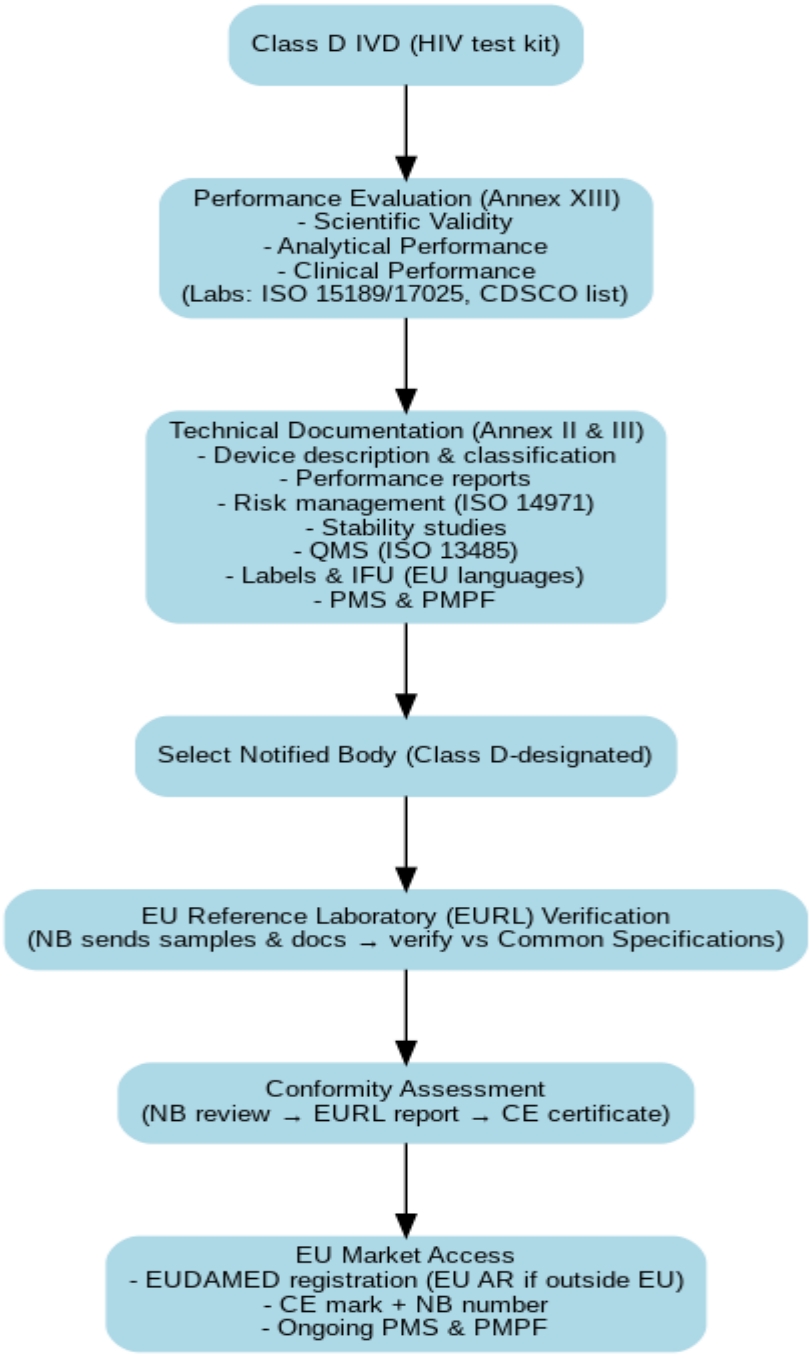

Figure 7: CE marking process for Class D IVDs under IVDR for EU Market Access.

This considerably multiplies the difficulty, the time and cost factor in performance testing, and this has caused some concerns by non-EU manufacturers regarding the access and availability of these testing centres (Kanti *et al.*, 2022). Moreover, the documentation should be structured and should be updated regularly as part of the device life cycle. Manufacturers

should also prepare an SSCP to give access to the general population through the European medical device database known as the EUDAMED (EUROPA, 2022).

2.4.4 Post-Market Obligations and Surveillance

The manufacturers put in place an effective PMS system, which includes a PMS plan for the systematic collection, analysis, and evaluation of data on the performance and safety of the device once it is placed on the market (Badnjević *et al.*, 2022). In the case of the higher-risk devices, a PMPF plan is also mandatory, which demands that manufacturers gather clinical performance data during routine use to ensure the ongoing safety, clinical benefit and performance of the device in real-world circumstances (Ali *et al.*, 2022; WHITE PAPER, 2025). This is theoretically comparable to the Stage 4 Continuous Process Verification in pharmaceutical production. There is a continuous process to monitor the real use of the product to establish that the product is up to the standards laid down and is still effective.

Table 5: Key Differences between IVDD and IVDR in PMS, PMPF, PSUR and Complaints Handling

Aspect	IVDD Requirements	IVDR Requirements
Post-Market Surveillance (PMS)	General obligation to monitor device performance after placing on the market; no specific format or frequency mandated.	Mandatory PMS plan for all device classes; structured and risk-based; PMS reports required for Class A & B and Class C & D
Post-Market Performance Follow-up (PMPF)	Not explicitly required; left to the manufacturer's discretion.	Mandatory for Class C & D devices; requires periodic PMPF evaluation reports and integration into the PMS system.
Periodic Safety Update Report (PSUR)	Not required under IVDD	Required for Class C & D devices; Must provide summary of results & conclusions of PMS and PMPF, benefit–risk analysis, and volume of sales; Updated: at least once a year for Class D, every 2 years for Class C; Submitted to Notified Body & made publicly available in EUDAMED.
Complaints Handling	Basic requirement to record and review complaints; no strict timelines or integration with the vigilance system.	Detailed, documented complaints-handling process; integration into PMS; linkage with CAPA; serious complaints reported via vigilance system within strict timelines
Regulatory Reporting	Less prescriptive; timelines are not standardised across all member states.	Harmonised EU-wide vigilance reporting through EUDAMED; fixed reporting timelines for serious incidents

Regulatory Oversight	Limited oversight; reporting is often national and fragmented.	Centralised oversight via EUDAMED, improving transparency and traceability of post-market data.

Other features that facilitate continuous monitoring are periodic safety update reports, vigilance reports and trend analysis. The regulatory authorities and NBs can use these mechanisms to observe the emerging risks (Laux *et al.*, 2024). Implementing these obligations cannot be done without a large investment in regulatory staff, data gathering networks, and product tracking systems, among other requirements by most manufacturers, particularly ones that have no prior experience in the EU market (Laux *et al.*, 2024).

2.4.5 Strategic Implications for Manufacturers

IVDR has significant strategic consequences for the IVD manufacturers, especially those outside the EU. The regulation requires a lot of planning in advance, cross-functional coordination and financial and operational resources (Yu *et al.*, 2022). In terms of product development, industries have to incorporate the regulatory needs into their design and validation process. Manufacturers are also forced to determine whether to continue to carry a large product line or drop products with a low margin, as they cannot sustain them economically with the new structure of compliance costs. This is especially pertinent to SMEs and exporters of countries such as India, whose margins are low and the cost of production is low (Mukherjee and Chanda, 2021). Some companies decided to specialise solely in the products that require the CE certification required by the IVDR. Moreover, a considerable number of manufacturers may be forced to think about the collaboration with EU Authorised Representatives, clinical research organisations, or consulting companies to pass the new requirements successfully (Law *et al.*, 2023). Services that outsource the regulatory compliance work have become more widespread, particularly by companies that either do not have a regulatory affairs department or are not accustomed to working in the EU submissions environment (Rajani *et al.*, 2022).

2.5 Role of the Indian IVD Industry and Export Landscape

2.5.1 Overview of the Indian IVD Sector

The IVD sector in India has become an essential part of the Indian medical technology ecosystem and plays an important role in population health programs and export diagnostic activities (Singh and Abrol, 2017). In 2024, the Indian medical device market is estimated to

be about USD 11 billion, with the IVD segment growing because of a rising number of communicable and non-communicable disease cases, a growth in testing infrastructure, and global demand for low-cost diagnostics (IBEF, 2025). With the support of the domestic demand and the foreign interest in low-priced testing kits like HIV test, malaria test, dengue test, and pregnancy test, the market has been increasing at a good rate (IBEF, 2025). In spite of such improvements, the Indian medical device industry is yet to be self-sustaining and continues to import large quantities of medical equipment (DOP, 2023a). Nevertheless, India has created a niche of exporting rapid diagnostic kits to nations in Africa, Southeast Asia and Europe (DOP, 2023a).

2.5.2 Regulatory Framework and Institutional Support

To improve quality standards and international competitiveness, India has strengthened its domestic regulatory framework of medical devices, and the number of Indian standards-based Notified Bodies authorised by CDSCO to determine compliance has increased to 13 in 2023 (CDSCO, 2023). According to the Medical Devices Rules, 2017, the Central Drugs Standard Control Organisation (CDSCO) is the central licensing authority and empowers State Licensing Authorities (SLAs) to oversee manufacturing site audits for Class A and B devices with the help of National Accreditation Board for Certification Bodies (NABCB) accredited Notified Bodies (CDSCO, 2017). These Notified Bodies, registered with CDSCO, do not issue licenses directly; they conduct quality system audits (ISO 13485:2016) and submit results to the SLA or CDSCO to issue licenses to manufacturers for Class A and B devices (CDSCO, 2017). However, for Class C and D devices, CDSCO undertakes direct conformity assessments and licensing. Table 6 compares the Medical Device Rules, 2017 and the EU IVDR 2017/746, highlighting key regulatory differences.

Table 6: Differences between Medical Device Rules 2017 CDSCO and EU IVDR 2017/746

Aspect	India – MDR 2017 (CDSCO)	EU IVDR 2017/746
Classification	Class A – Low risk Class B – Low-moderate risk Class C – Moderate-high risk Class D – High risk	Class A – Low risk Class B – Moderate risk Class C – High individual risk Class D – Highest public health risk
NBs and Audit	State Licensing Authorities (SLA) oversee Class A and B devices, while the Central Licensing Authority (CLA) handles Class C and D devices.	EU-designated Notified Bodies (NBs) perform audits for Class B, C, and D IVDs; Competent Authorities supervise the process.
Audit Frequency	At the time of licensing and renewal (every 5 years), possible surprise inspections	Initial conformity assessment, then annual surveillance audits, plus unannounced audits at least every 5 years (or more often for high-risk devices)
Audit Scope	Compliance with MDR 2017, ISO 13485 QMS, manufacturing facility inspection, sample testing, review of Device/Plant Master File, verification of labelling and performance evaluation reports	Covers QMS (ISO 13485 + IVDR-specific), design controls, performance evidence, risk management, PMS, vigilance, UDI compliance, and technical documentation review
Clinical/Performance Data Review	Performance evaluation reviewed mainly for Class C & D; often document-based	Mandatory review of scientific validity, analytical performance, and clinical performance for all higher-risk IVDs (Classes B, C, and D)
PMS & Vigilance in Audit	Checked during renewal audits; CDSCO verifies PSUR and complaint records	Review of PMS plans, PSUR data, trend and vigilance reports, with the Notified Body ensuring corrective actions are carried out
Regulatory Document Verification	Verifies DMF, PMF, import/manufacturing licenses, and test reports	Verifies Annex II & III technical documentation, CE certificate, NB opinions, EUDAMED entries
Outcome of Audit	License grant/renewal; corrective action requests; possible suspension	CE marking approval/maintenance; NB may suspend or withdraw the certificate if non-compliance is found

Recently, CDSCO has revised its list of approved laboratories specialising in quality, safety and compliance, and authorised to perform lab-based testing. Currently, this regulatory body has cleared 9 more medical device testing laboratories, and thus the number has risen to 39 (Jayati Dubey, 2024). Through this, they may be able to carry out the test and assessment of the medical devices on behalf of the different manufacturers, as it is stipulated in the form MD-40 under the MDR, 2017 (Jayati Dubey, 2024). In the case of Class C and D, IVD Manufacturers must adhere to specified analytical and clinical performance requirements in India through labs approved by CDSCO, and this is in context with the increased focus on rigorous, standardised performance testing IVDR (CDSCO, 2025),(Strategist, 2025). As a partial compliance with the international standards adopted, the Indian pharmacopoeia commission and the central drugs standard control organisation (CDSCO) have revised their standard on the QMS and performance-based acceptance tests requirements (Yadav *et al.*, 2021).

Nonetheless, even though such efforts have improved the credibility of the Indian internal regulation, a great discrepancy exists between the frameworks of India with those of the more stringent EU IVDR 2017/746. The CDSCO is primarily responsible for implementing regulatory control in India. It has set clinical performance and PMS requirements, but these are not as formalised, comprehensive, or required as those under the EU regulatory framework. Clinical performance studies and PMS systems are not yet required by Indian officials to meet the same standards as those required by EU rules (Manu and Anand, 2022). As a result, Indian manufacturers aiming for CE certification may struggle to meet IVDR requirements for documentation, performance evaluation, and traceability due to institutional limitations and a lack of aligned regulatory expectations (Manu and Anand, 2022).

2.6 Strategic Barriers to EU Market Access

Compared to EU manufacturers, Indian IVD exporters have numerous obstacles to overcome during the process of entering the market through the IVDR framework. The shortage of EU-recognised NBs is one of the most important issues to be addressed (Farrugia, 2023). By the beginning of 2024, a small number of NBs received authorisation to conduct IVD device testing under IVDR, which causes extended delays (EUROPEAN COMMISSION, 2025b). For the Indian companies, in particular the SMEs, this means a lot of delays in the certification process, time uncertainties, and extra administrative costs.

2.6.1 Notified Body Shortages and Capacity Constraints

One of the biggest market blocks when it comes to IVDR is the small number of designated NBs. At the beginning of 2024, the European Commission recognised 12 NBs to conduct IVDR conformity assessment (Jurczak *et al.*, 2025). This is a huge drop from 22 to 12, compared to what was in operation under IVDD, and it is insufficient as compared to the sharp increase experienced in the demand for third-party assessments due to the increased number of devices requiring assessment. There was a significant decrease in the number of designated Notified Bodies (NBs) from about 22 NBs during the IVDD were reduced to less than 17 under IVDR as a result of more strict regulatory requirements, tighter qualification standards, and complex re-designation processes. With IVDD, designation was less demanding as only an estimated 20% of the IVDs posing high risks necessitated NB oversight. IVDR, on the other hand, requires the assessment of 80% - 90% of the devices by NB, with full technical documentation, detailed performance evaluation, and post-market surveillance (IQVIA, 2025). NBs are currently required to prove in-house competence in all IVD categories, have well-developed quality management systems, and be completely independent of the manufacturers, all of which most IVDD-era NBs were unable to achieve or deem financially unfeasible. Indeed, even the re-designation procedure alone is a lengthy process as it is accompanied by auditing of national authorities, a joint evaluation arranged at the EU level and the official authorisation, which may last 12-18 months.

These limits especially disadvantage Indian exporters, because NBs will often focus on the current clients, and in particular, the large manufacturers of the EU. Non-European businesses, such as Indian-based companies, have to wait durations that are often more than 12 to 18 months to obtain a review slot (MDCG, 2019). Under the Medical Device Regulations and In Vitro Diagnostic Medical Device Regulation, manufacturers based outside of the EU are obliged to appoint an Authorised Representative within the EU when they place their devices on the European market (EMERGO, 2025). Many exporters are blocked off from the EU market, even though they have worthy goods ready to sell, since they lack pre-existing contacts and on-the-ground representatives to facilitate the process (EMERGO, 2025).

2.6.2 Technical Documentation and Compliance Gaps

The technical documentation is another barrier to market access due to the complex and continuously evolving requirements of IVDR. The manufacturers should provide detailed documentation related to design dossiers, clinical data, performance evaluation reports (PERs), and post-market surveillance (PMS) plans (Badnjević *et al.*, 2022). Class D devices, including the HIV test kits, need to be tested in the EU-authorised reference laboratories, and this increases the logistical and financial burden on the Indian exporters (Unitaid, 2018). The performance evidence gathered should meet EU clinical requirements, like valid scientific and statistically sound data. It poses a serious obstacle to numerous companies that lack clinical research departments or have no access to certified partners (Polishchuk, 2023).

2.6.3 Cost Burden and Economic Viability

The high cost of IVDR compliance is one of the biggest barriers to entry into the EU (Idink, 2025). It is estimated that CE marking costs increase five to ten times under IVDR than under IVDD (MedTech Europe, 2025). These expenses include NB charges, consulting services, clinical testing, record preparation and the implementation of the activities of a post-market surveillance system. Some manufacturers have opted to exit the EU market or postpone applications indefinitely based on the poor returns on investment (MedTech Europe, 2025b); (OECD, 2017). Such a tendency has been observed not only by Indian exporters but also by smaller companies based in the EU, signifying a systemic problem with the implementation of such regulation (EMERGO, 2022). It destroys previous investments and puts companies in a damaging position compared to those competitors who did use the transitional provisions of the IVDR.

2.6.4 Administrative and Digital Infrastructure Limitations

The IVDR requires manufacturers to enrol their products in the European EUDAMED database, post summaries on the product safety and performance, and gain traceability of their products using UDI systems (Thavayogarajah, 2021). These demands are further mixed with constraints of infrastructure and capabilities by the Indian exporters. Most of them lack built-in digital frameworks and IT content for EU-formatted workplace regulations. Intermittent internet connection, absence of data security measures and general ignorance of European data management regulations, including the General Data Protection Regulation

(GDPR), also make it difficult to be compliant (Khan, 2025). Therefore, a technical compliance product can still be delayed because of non-compliance with digital documentation and reporting standards.

2.6.5 Documentation and Technical Compliance Challenges

The difference between the IVDD and IVDR is associated with the creation of technical documentation and PERs according to the requirements that were established under the IVDR (Kahles *et al.*, 2023). The Indian companies in the IVD industry usually use simplified documentation in the local/regional markets. Nevertheless, with IVDR, such a vast quantity of clinical and analytical data has to be filed that it should accompany documentation according to the EU templates and language criteria (Charrière and Pazart, 2023). The Class D devices need to go to the EU reference laboratories to get validated by them, and most Indian companies are not able to do that (Manu and Anand, 2022). Also, among Indian exporters, integration of PMPF and PMS systems is still low, mainly because of the restriction to costs and the absence of EU-ready data collection systems (Nwokike, 2023). The European NBs also require more traceability in devices and prefer devices that have a UDI System and expect the manufacturers to post their safety and performance summaries on the EUDAMED database (Thavayogarajah, 2021). These requirements are challenging to fulfil most of the time for leading Indian exporters due to limited domestic IT and regulatory infrastructure (Khan and Goel, 2024).

In addition to this, the GSPR are a key part of the European Union regulations governing medical devices and in vitro diagnostics, as specified by the Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostic Regulation (IVDR) 2017/746. GSPR establishes the required safety and performance requirements to which IVDs and medical devices must comply before being released onto the EU market (Ghatge *et al.*, 2023)

2.6.6 Preparedness and Response Strategies

Indian IVD manufacturers have started to reorganise their manufacturing with the aim of complying with the EU expectations. Companies are using ISO 13485-certified quality management systems, regulatory affairs experts, and European consultants to help them develop IVDR-compliant documentation (Kivimäki, 2022). Bigger companies that have experience in exporting are in a better position to adapt, but SMEs tend to depend on donor-

funded capacity-building efforts or even a joint venture with distributors based in the EU (George, 2021).

The Indian government has undertaken strengthening activities of the regulation through the National Medical Devices Policy, in an initiative of regulatory harmonisation, skills development and incentives to export-oriented companies in 2023 (DOP, 2023b). These policies are fairly new and following them is voluntary, but they are a reflection of good intent. The lack of a national framework for ensuring EU-compatible performance review and post-market data gathering capacity restricts the action of IVD device producers in having internal capabilities (EUR, 2017). In addition to this, other associations in the industry have also urged the formation of India-EU regulatory connection groups and expedited schemes that grant CE certification in India (Pandya and Leal-Arcas, 2024). These include the Association of Indian Medical Device Industry (AiMeD) and Confederation of Indian Industry (CII).

2.7 Analysis of Organisational Adaptation to Regulatory Change

2.7.1 Transformation of Quality Management Systems

Improvement of QMS is one of the short-term organisational responses to IVDR (Gamarra and Karen, 2025). At present, under the IVDD, smaller companies may frequently be able to use an elementary or semi-formalised system, especially when they are self-proclaiming compliance. The IVDR requires everybody to apply a quality management system relevant to the ISO 13485:2016, not only the manufacturers operating within the EU, but also the non-EU manufacturers who export to the EU/to the region (Niclas Svensson, 2023). This new trend is creating a much bigger burden on the smaller manufacturers whose operations need to be formalised, to be audited by a third party and to have excellent documentation of the product life-cycle. This standard addresses the issues of risk management, development and design controls, traceability, supplier management and PMS. To satisfy these demands, Indian IVD companies are embarking on applying digital tools and structured processes to QMS (Kumar *et al.*, 2025). Documentation operations have undergone centralisation and version control, and internal audits and training schemes have been aligned to the EU standards (Kahles *et al.*, 2023). Companies which used to be reactive in their approaches to

compliance will need proactive system management with QMS, which is not a regulatory but an organisational program essential(Finocchio, 2025)

2.7.2 Establishment of Dedicated Regulatory Affairs Teams

The other adaptation that points to change as a critical element is the development and growth of in-house regulatory affairs teams. The role of regulation in most Indian companies was spread informally between departments prior to IVDR (Manu and Anand, 2022). Nonetheless, the IVDR complexity and the number of things to be submitted have caused the manufacturers to hire or even to train new specialists in European regulations regarding medical devices (MedTech Europe, 2025b).

Those teams are asked to collect technical documentation, to prepare PERs, to deal with NBs and to facilitate the fulfilment of the post-market requirements (PMS and PMPF) (Valla *et al.*, 2021). Alongside this, the heightened EU-regulator attention, supported by MDCG guidelines, has necessitated real-time awareness of updates, NB interpretations, and clinical evidence. This has made regulatory affairs one of the key strategic functions in companies dealing with IVD products since regulatory affairs now have a direct impact on the development timing, product launch order and decisions on how to invest in the R&D (Kearney *et al.*, 2021).

2.7.3 Strategic Reassessment of Product Portfolios

Organisations are strategically reviewing their product portfolio regarding regulatory complexity and the costs of IVDR. A lot of companies are phasing out low-margin or low-volume goods that would cost too much to make IVDR certified (MB, 2022). They are concentrating on a limited number of areas of high demand, such as diagnostic kits that include Class D HIV kits and Class B pregnancy kits that have the potential to be marked with CE and have commercial feasibility. The rationalisation process is an economic and regulatory process in which the various manufacturers strive to distribute their limited resources, both regulatory and economic (Foster and Thelen, 2024).

2.7.4 Investment in Digital Infrastructure and Training

In order to address the post-market and traceability obligations in IVDR, companies have funded digital systems that are able to facilitate UDI management, adverse event reporting, and real-time documentation updates (Mondal, 2025). These systems play such an important

role in meeting the EUDAMED registration by showing the continued safety and performance of the products. The EU regulation, documentation language and monitoring requirements have to be complied with by organisations which require their understanding by their employees (Mökander *et al.*, 2022). This will guarantee that adherence to the requirements of the IVDR will become a part of all departments of the company, including research and development departments, logistics departments, and others, with the quality being embedded into the product. This is consistent with the principles of Quality by Design, in which the regulations are kept aligned throughout the whole product lifecycle (Mökander *et al.*, 2022). Figure 8 illustrates the sequential CE marking process under IVDR, from R&D and prototype development through verification, regulatory review, manufacturing, and post-market surveillance, ensuring compliance, safety, and continuous performance monitoring.

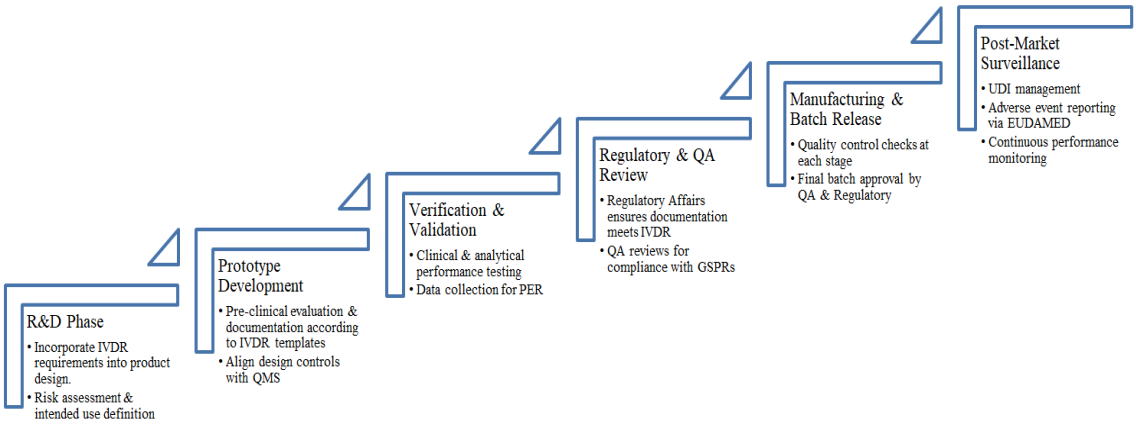

Figure 8: Company Process

2.8 Summary

This chapter has considered the international legal environment that exists due to the EU IVDR 2017/746, on its structural requirements and the effects of the same on Indian IVD exporters. It examined the intricacies of compliance, organisational adjustments and strategic challenges which impact market access. The literature shows that there are immense obstacles, especially for SMEs, yet no empirical studies examine the adaptation requirements at the manufacturer level within India. The conceptual framework created for this study incorporates significant variables and relationships, aiming to fill the identified gaps in the literature. The context of the research methodology presented in the following chapter is

informed by this review, and it sets out reasons why it is necessary to investigate the experiences of Indian IVD regulatory professionals.

Chapter 3
Research Methodology

Chapter 3: Research Methodology

3.1 Introduction

This chapter is focused on the methodology section, which has been conducted to determine the Regulatory Strategy and Market Access Challenges under EU IVDR 2017/746 and what issues are being experienced by the organisations to comply with the EU market. The research will aim to come up with practical knowledge regarding the strategies to utilise regulatory compliance and market access by gathering first-hand experience of professionals involved in working in regulatory affairs and quality assurance functions of Indian IVD companies. Furthermore, during the work, the research onion model (shown in 9) has been applied, which not only helps to identify each and every stage of the methodology but also helps in the implementation of each phase in an efficient manner (Deshpande and Magerko, 2024). Moreover, this chapter provides the information related to research philosophy, approach, strategy, choice, time horizon, data collection, and analysis approaches.

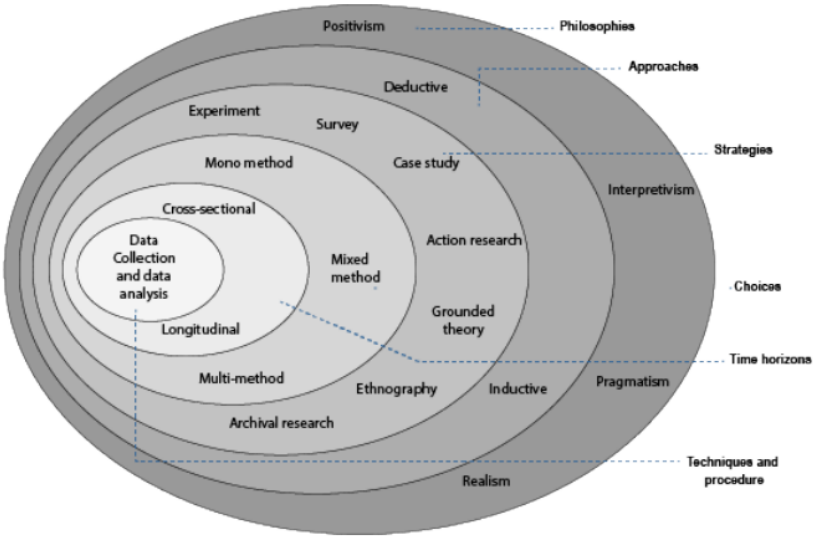

Figure 9: Research Onion Model

3.2 Research Philosophy

In research, the way of perceiving knowledge depends on the philosophical background of the researcher, which defines the general design and approach to the interpretation of the data. In this research, the philosophy is interpretivism philosophy, which is suitable to study perceptions, interpretations, and reactions of Indian IVD manufacturers to complicated regulatory changes under the EU legislation IVDR 2017/746. This philosophy is appropriate

because it helps to analyse regulatory approaches, organisational changes and lived professional experiences (Maksimović and Evtimov, 2023). In addition, it focuses on analysing social phenomena within the context of individual and group subjectivities.

Moreover, this philosophy helps measure a phenomenon in absolute and universal terms. This link is to the purpose of the study, which reflects the detailed and diverse reactions of Indian exporters to the changing EU regulatory landscape. Furthermore, interpretivism also allows in-depth interpretation of the internal logic, problems and decision-making processes that define regulatory compliance. In addition, it is relevant to this study as it requires the insight of professionals who work in different organisational settings (Junjie and Yingxin, 2022).

Furthermore, the traits of pragmatism can also be found in the research design, where a mixed-methods strategy is used. This pragmatic is flexible and enables the study to make practical conclusions as well while still being based on real-life evidence. Through the combination of interpretivism and pragmatic components, the study covers the subjective nature and the larger trends that are needed to comprehend the manner in which Indian IVD companies find their way in the EU IVDR compliance.

3.3 Research Approach

The inductive research approach used in this study was suitable because it helps to conduct the research, which is based on a dynamic regulatory environment (Kumar and Ujire, 2024).. This approach helps to gain the experience of Indian exporters of in vitro diagnostic (IVD) products in the European Union, In vitro diagnostic regulation (IVDR) 2017/746. However, the regulation introduced new challenges to non-EU manufacturers, so the inductive method provides a chance to formulate context-sensitive insights out of the information gathered.

During the inductive research approach, different research questions were formed based on the objective, which not only helps to conduct the study but also guides to achievement of the research objectives (Eger and Hjerm, 2022). In this, different research questions such as "What are the organisational and strategic changes implemented by Indian IVD manufacturers to comply with EU IVDR 2017/746, particularly in regulatory affairs and quality assurance?", "***How do key compliance challenges, such as access to Notified Bodies, resource limitations, and post-market surveillance (PMS), encounter during the IVDR transition?", "How are Indian manufacturers updating technical documentation,***

including Performance Evaluation Reports (PERs) and clinical evidence, to align with IVDR?", and "What is the impact of IVDR on CE marking timelines and overall EU market accessibility for Indian IVD exporters?" are formed. These research questions help to analyse the respective strategic adjustments of the Indian IVD manufacturers, like regulatory compliance and the accessibility to the market in response to the EU IVDR 2017/746 regarding Class D HIV kits and Class B pregnancy kits.

3.4 Research Strategy

This research has used a survey research strategy to help in the collection of data with the help of a survey among the professionals in in vitro diagnostic (IVD) manufacturing companies in India, especially employed in regulatory affairs and quality assurance in these companies. The use of a survey strategy was suitable because it helps to attract a relatively large group of participants to participate in the study (Anahita Ghanad, 2023). In addition, this strategy facilitated the systematic and efficient collection of data in a significant manner. Due to the geographic distribution of participants and a narrow speciality of the subject compared to the width of the issue, like compliance with the EU IVDR 2017/746, the survey was the most convenient and feasible method of obtaining relevant conditions.

The survey considered both closed-ended and open-ended questions, which helps to collect the information efficiently. In addition, the web-based platform (Google Forms) has been considered to conduct the survey and allows participants to participate conveniently, taking into account time limits and promotes the possibility of anonymity and responsible usage of data. Therefore, it represents that the survey approach is an appropriate approach which helps to investigate the way Indian IVD exporters are adjusting to the challenges of EU IVDR in terms of organisational adaptation, documentation, and certification of CE experience, with a limited amount of time and resources required.

3.5 Research data type

This research used mixed research methods in which both qualitative and quantitative information were considered. This method was used in order to gain in-depth information on how the Indian IVD producers are adjusting to the challenges of the EU IVDR 2017/746. However, complex in nature, revolving around regulatory compliance, strategic decision-

making, and organisational transformation, combining the numeric trends and the context are the major challenges which directly impact the findings (Mulisa, 2022).

Therefore, the quantitative data have been gathered with the help of closed-ended survey questions, which allowed us to determine the pattern and generalisations on the CE marking timelines, accessibility to the NBs, and the compliance activities. On the other hand, qualitative data gained with the help of open-ended questions provided their individual experiences, difficulties, and reflections concerning documentation, PMS, and the way of strategic adjustment. A mixed research choice helps to gain information about the regulatory behaviours of the Indian exporters. In addition, it helped to make the study empirical and thought-provoking, particularly professionally and academically profound.

3.6 Time Horizon Approach

This study used a cross-sectional time horizon approach, which represents the collection of data in one period of time to understand how the Indian IVD exporters were responding to the regulatory requirements of the EU IVDR 2017/746. The cross-sectional approach is considered because it helps to describe the present state of organisational practices, compliance behaviour and strategic reply in a certain periodic and regulatory setting. In addition, it allowed current participants to experience and perceive in real time since the deadlines of the IVDR compliance were active and constantly developing. Moreover, a cross-sectional time horizon is also appropriate because of pragmatic reasons, like access to participants is limited over a long period(Mishra and Alok, 2017). In addition, it helps to collect the data through surveys and assists in analysing it on time. However, this method failed to allow discerning the changes or evolution over time, but provided the opportunity to understand how companies were adapting to the regulatory changes during a crucial period in the process of IVDR transition.

3.7 Research Technique

3.7.1 Data Collection

The collection of data is one of the important aspects which helps to justify the research objective and helps complete the study significantly (Dawadi *et al.*, 2021). In this research, a structured online survey has been considered, which helps to collect the relevant information and aims to collect both qualitative and quantitative information. In addition, it

helps to measure the respondents working in the sector of manufacturing in vitro diagnostics (IVD) in India. The survey questionnaire was made, which is related to the research objectives, and focused on the organisational adjustments, regulatory documentation procedures, and barriers to market access in the EU IVDR 2017/746. In addition, this data collection technique is suitable due to anonymity, geographic dispersion of the participants, and the aspect of time constraints.

Moreover, during the collection of the data, the questionnaire was composed to include both closed (multiple-choice questions, Likert scales) and open-ended questions. It helps to collect the participants' independent descriptions of their experiences and views. Moreover, it helps to measure patterns like how common the delay of the CE marking is or how large the changes in QMS Thus, the survey was piloted with two regulatory professionals before being sent out to ensure that it is worded, relevant and functions effectively technically. Depending on their suggestions, minor changes were implemented in the question formulation. The data collection was conducted within three weeks, and the participants were reminded to send the questionnaire via LinkedIn, professional email groups, and discussion boards for professionals in order to increase the response rate. Furthermore, Data was only stored safely, and only the researcher had access to it, which complies with GDPR and institutional ethical principles.

In addition, the survey questions were also directly linked to the purpose of the study and so the answers would be completely analytical. This is a robust and ethical data collection process that facilitated the researcher to obtain the current regulatory practice and the challenges that the Indian IVD exporters are encountering in the EU IVDR regulating environment. Furthermore, it helps to gain information from professionals who are working in the area of IVD devices.

3.7.2 Sampling

The research utilised the non-probability purposive sampling method to consider those participants who are particularly expert in regulatory compliance in the Indian in vitro diagnostic (IVD) market. A purposive sampling was conducted only on participants whose professional experience was related to the specific requirements of the proposed project and considered only those working in the regulatory areas, quality assurance and compliance in the EU IVDR 2017/746. The number of workers in the Medical Devices & Products market

of India would reach 1 million in 2025 (Statista, 2025b). Once having computed the data using the 95% Confidence Level and 5% margin of error, the sample is 385 Indian IVD employees operating in the area of Regulatory Affairs, Quality Assurance and Compliance. However, because of the limitations of time, access and logistics, the final sample of responses was researched, all of which followed the inclusion criteria of the study. This is a very low number as compared to the statistical ideal; however, it is enough regarding the exploratory and qualitative aspects of this study. These participants had experience in the industry with a direct or indirect role in processes that concern the regulation of IVDRs, including CE marking, its documentation, and post-market surveillance. A total of 385 participants were required to achieve a 95% confidence level with a 5% margin of error. However, 171 valid responses were received. This results in a reduced confidence level to 85% and increased margin of error to 5.51%, which may impact the generalisability of the findings.

Moreover, the respondents were selected using professional sites like LinkedIn and corporate connections, and the eligibility was determined using a screening questionnaire. In addition, these participants know about the adaptation to regulations and entering the market, which is also in line with the research objectives. Moreover, the following inclusion and exclusion criteria are considered during the sampling and data collection. Table 7 outlines the Inclusion and Exclusion Criteria of the participants.

Table 7: Inclusion and Exclusion Criteria

Criteria Type	Inclusion Criteria	Exclusion Criteria
Professional Role	Participants must be employed in the Indian IVD sector with responsibilities in Regulatory Affairs, Quality Assurance, or Compliance with relevant years of experience.	Individuals working in unrelated fields or outside the IVD sector.
Experience	Decent professional experience in the IVD or medical device regulatory domain.	Professionals with no relevant experience in regulatory or quality functions.
Geographic Scope	Based in India and employed by Indian IVD manufacturing/exporting companies.	Individuals based outside India or working for foreign entities do not export from India.
IVDR Involvement	Must have experience or direct involvement in EU IVDR compliance, CE marking, or related processes.	No exposure or role in EU regulatory compliance, particularly with IVDR 2017/746.
Consent & Participation	Voluntary participation with informed consent provided through the survey platform.	Individuals unwilling to participate or who did not provide consent for data use

3.8 Data analysis

The mixed analysis (quantitative and qualitative) method has been used in this work, which helped to evaluate the structured survey data (Nasir and Sukmawati, 2023). During the analysis, Microsoft Excel was initially used to clean, tabulate and visually summarise the quantitative data, which was obtained with the help of closed-ended questions. Furthermore, analysis was further performed on the data in terms of relationships between important variables of concern to the research questions using more of the IBM SPSS Statistics. Moreover, the Correlation analysis was considered as a statistical test which helps to understand the relationships between variables like firm size and CE certification preparedness. In addition, the linear regression was performed, which helps in determining the influence of attentiveness towards the roles of regulatory compliance on the probable timing of gaining EU market access. Moreover, the frequencies and percentage measures, and cross-tabulations, were used to describe the patterns in terms of technical documentation, access to the NBs, and post-market surveillance implementation.

Furthermore, the thematic analysis was used in analysing the qualitative data, which was collected by giving open-ended survey questions. During the thematic analysis manual reviewing, coding and categorising of the responses under themes were carried out with the help of the six-phase design principle of Braun and Clarke (Naeem *et al.*, 2023). In addition, during the thematic analysis, first the data were categorised according to code and then analysed based on the developed themes. The following themes are developed in this work, which help to evaluate the qualitative information (Table 8).

Table 8: Themes description

Theme	Description	Codes
Regulatory Uncertainty	Participants expressed confusion or a lack of clarity regarding IVDR interpretation and expectations.	Ambiguous guidelines, evolving NB requirements, and misaligned communication
Documentation Challenges	Difficulties in preparing technical files, clinical evidence, and performance evaluation reports.	Incomplete PERs, Class D documentation complexity, and EU template unfamiliarity
Notified Body Access Constraints	Limited ability to engage with IVDR-designated Notified Bodies within reasonable timeframes.	Long waiting periods, prioritisation of EU companies, and communication barriers
Strategic Product Prioritisation	Firms are selectively pursuing CE marking for high-volume or high-margin products only.	Withdrawal of low-margin kits, focus on Class B over Class D, and resource reallocation.

Therefore, it represents that both data analytics, such as the employment of SPSS to interpret quantitative patterns and thematic analysis to gain qualitative explanations of data, allowed for explaining the data comprehensively. In addition, this analysis helped to analyse the strategic abilities of Indian IVD manufacturers, in fields of regulatory compliance and market access to the EU IVDR 2017/746, respectively, to Class D, HIV, kits and Class B pregnancy kits. Furthermore, it helps to determine the impact of IVDR on CE marking timelines and overall EU market accessibility for Indian IVD exporters.

3.9 Ethical Consideration

The ethical consideration was important in this research and was considered in every step of this research. In addition, it helps to get a formal approval of ethical management processes involving the collection of data before conducting the data collection exercise, following the institutional guidelines (Boistrup and Selander, 2021). Each of the participants was given a Participant Information Leaflet (PIL) stating the aim of the research, volunteer participation, whether the data would be confidentially handled and data withdrawal without any penalty. Moreover, the General Data Protection Regulation (GDPR) principles were also considered, which represent that all information was stored in password-enabled devices and only the researcher had access to the storage (Comandè and Schneider, 2022). The study did not collect any audio or video data, and all answers were academic. The respondents were guaranteed privacy, integrity, and respect for their data. These ethical considerations ensured that the research earned the best academic standards of integrity, openness and care regarding the participants in the course of the research.

3.10 Conceptual Framework

The conceptual framework of this research is built to understand the correlation between the regulatory reforms brought in the EU through EU IVDR 2017/746 and the market access performance of Indian IVD exporters, especially the manufacturers of Class B and Class D rapid diagnostic kits (Figure 9). It shows how inward regulatory pressures condition the outward strategic and organisational actions and the capacity to gain and maintain access to the EU market. The EU IVDR 2017/746 regulatory requirements, which involve the function of risk classification, performance, clinical evidence and PMS and show the conformity of medical devices to the CE certification standards, will constitute the independent variable in

this study (Figure 10). These demands serve as an exterior pressure that makes Indian IVD manufacturers change their operation framework and regulatory frameworks (Baumgartner *et al.*, 2023).

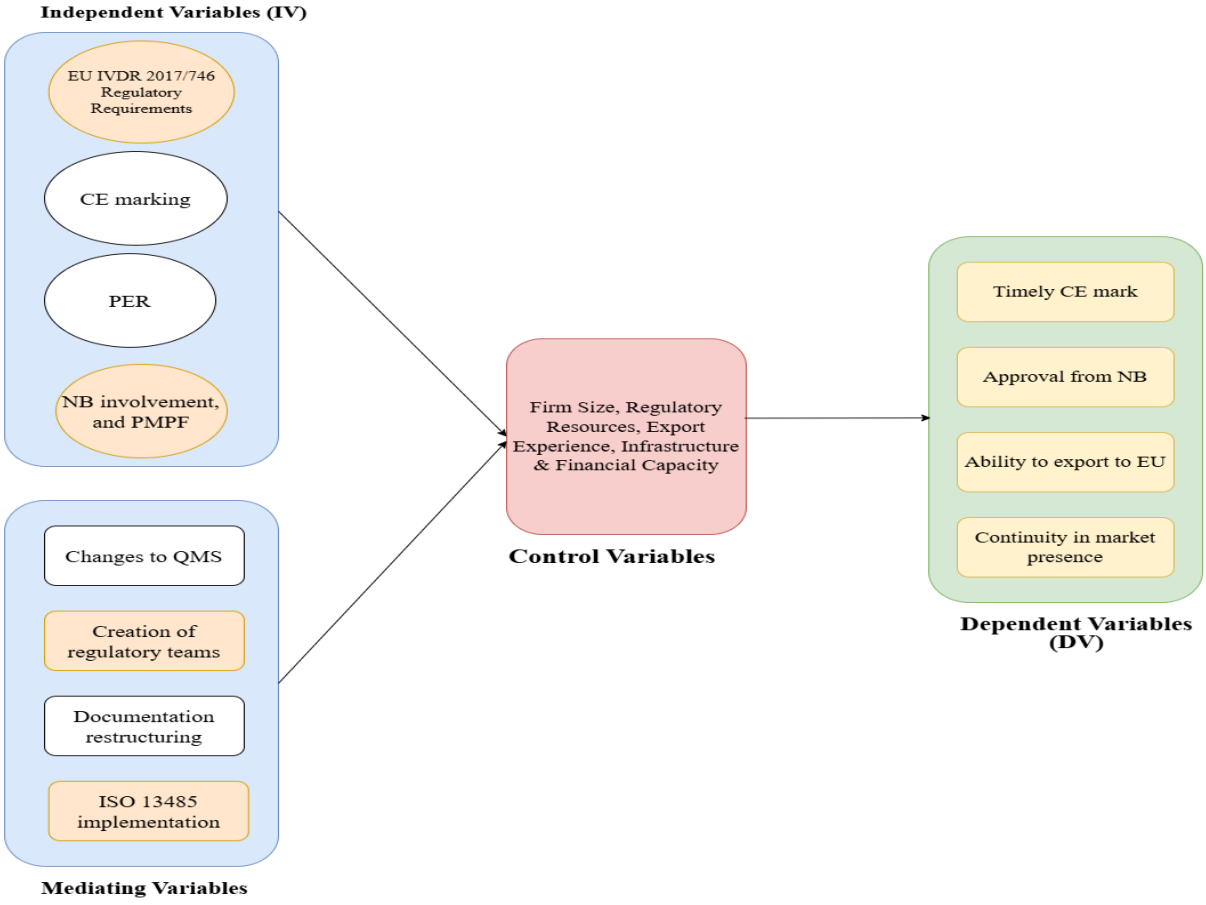

Figure 10: Conceptual Framework

The dependent variable involves the market access success of Indian IVD exporters, and it is operationalised by how able individual exporters are to progressively receive a timely CE mark, fulfil their regulatory expectations to maintain EU regulations, as well as to gain or broaden market volume/share within the EU (Spitzenberger *et al.*, 2022). Achievement of market access is considered a conditional issue, depending on the strategic response of these companies to the regulatory environment that keeps changing. The control variables can be company size, current regulatory framework, exposure to the international market, and financial resources. They can change the capacity of adaptation of a business/company, but they are not changed by the IVDR. Keeping these factors constant throughout the analysis,

the model removes the nonspecific effect of regulatory change on compliance behaviours and outcomes.

Table 9: Independent and Dependent variables used in the conceptual framework

Component	Variable/Element	Role in Framework	Indicators
Independent Variable	EU IVDR 2017/746 Regulatory Requirements	External driver of organisational change	Risk classification (Class B/D), PERs, PMPF, CE certification, NB involvement
Mediating Process	Organisational and Strategic Adaptation	The mechanism through which companies respond to regulation	Updated QMS (ISO 13485), documentation restructuring, staff training, hiring consultants
Dependent Variable	Market Access Outcome	Final measurable impact	Timely CE mark, ability to export to the EU, sustained compliance, NB approval
Control Variables	Firm Characteristics	Factors held constant or used for comparison	Firm size, regulatory team strength, prior EU market experience, and financial capacity

3.11 Conclusion

The above chapter described the methodological framework which helped to determine how Indian IVD manufacturers are reacting to the EU IVDR 2017/746. The above chapter provides information about the interpretivism philosophy, the inductive and mixed methods approach used in this study. In addition, a structured survey was used, which helps to gather quantitative and qualitative information. In data analysis procedures, thematic analysis and SPSS statistical testing were applied. Therefore, all these methodological approaches helped to conduct the research and significantly assisted in achieving the research objective.

Chapter 4
Results and Findings

Chapter 4: Results and Findings

4.1 Introduction

This chapter represents the findings established in the data analysis and helps to resolve the research purpose of assessing the preparedness, challenges, and strategic responses of Indian In Vitro Diagnostic (IVD) manufacturers to regulations under the European Union In Vitro Diagnostic Regulation (EU IVDR 2017/746). These findings have been structured based on the research objectives and questions of the study, which means that there is a strong connection between the gathered data and the desired results. SPSS was used to carry out both descriptive and inferential statistical analyses in an attempt to detect patterns, relationships, and differences between key organisational and regulatory variables. Descriptive statistics describe the characteristics of the participants and the organisations, whereas inferential tests, such as one-way ANOVA, correlation, linear regression, independent-samples t-tests, and chi-square analysis, examine the associations, predictors, and comparisons of the groups. Qualitative responses have been included in the discussion chapter in order to create relevant depth.

4.2 Quantitative analysis

4.2.1 Analysis of the Participant Profile and Eligibility

In this section, the survey sample screening was carried out, which helped to identify Questionnaire respondents who are well placed to respond to the issue of compliance with IVDR among the Indian IVD creators. Out of the total 182 survey returns, 181 answered the employment screening question appropriately. In this, 175 respondents (96.7%) indicated that they were presently employed within the Indian IVD manufacturing industry, but 6 (3.3%) answered that they are not employed within the Indian IVD manufacturing industry, and 1 response was not answered (Table 10).

Table 10: Current working situation

Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	175	96.2	96.7	96.7
	No	6	3.3	3.3	100.0
	Total	181	99.5	100.0	
Missing	System	1	.5		
Total		182	100.0		

Furthermore, the question “Do you have at least two years of professional experience in Regulatory Affairs, Quality Assurance or Compliance inside the IVD sector?” was considered as screening question in which 171 participants (97.7%) answered “Yes” they have at least 2 year professional experience and 4 participants (2.3) answered “No”. Thus, after the final screening, 171 participants were considered for further analysis (Figure 11 and Table 11).

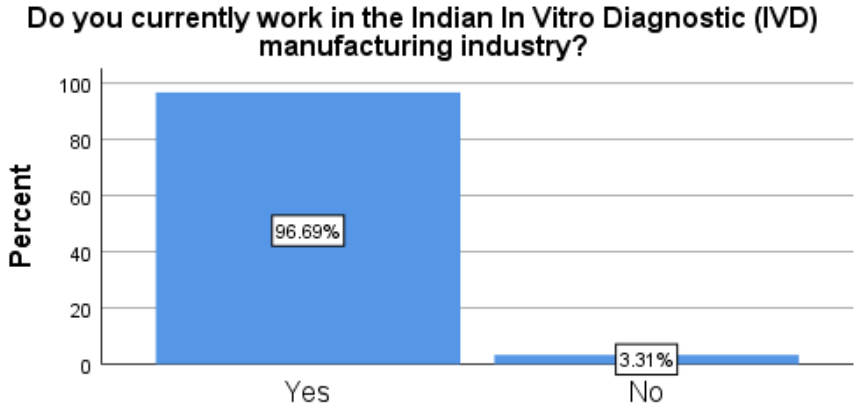

Figure 11: Current work status of participants

Table 11: Professional experience

Do you have at least two years of professional experience in Regulatory Affairs, Quality Assurance or Compliance inside the IVD sector?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	171	94.0	97.7	97.7
	No	4	2.2	2.3	100.0
	Total	175	96.2	100.0	
Missing	System	7	3.8		
Total		182	100.0		

However, there are 7 participant who did not provide their responses (Figure 12). The sample in which these screening results occurred proves that the dataset is mostly composed of experienced regulatory/quality individuals in the Indian IVD industry. In 182 responses, 11 were missing as 1 respondent disagreed on consent, 6 respondents do not work in the Indian IVD sector, and 4 respondents did not have the experience of at least 2 years in this sector. Thus, during the analysis, 171 valid responses were considered.

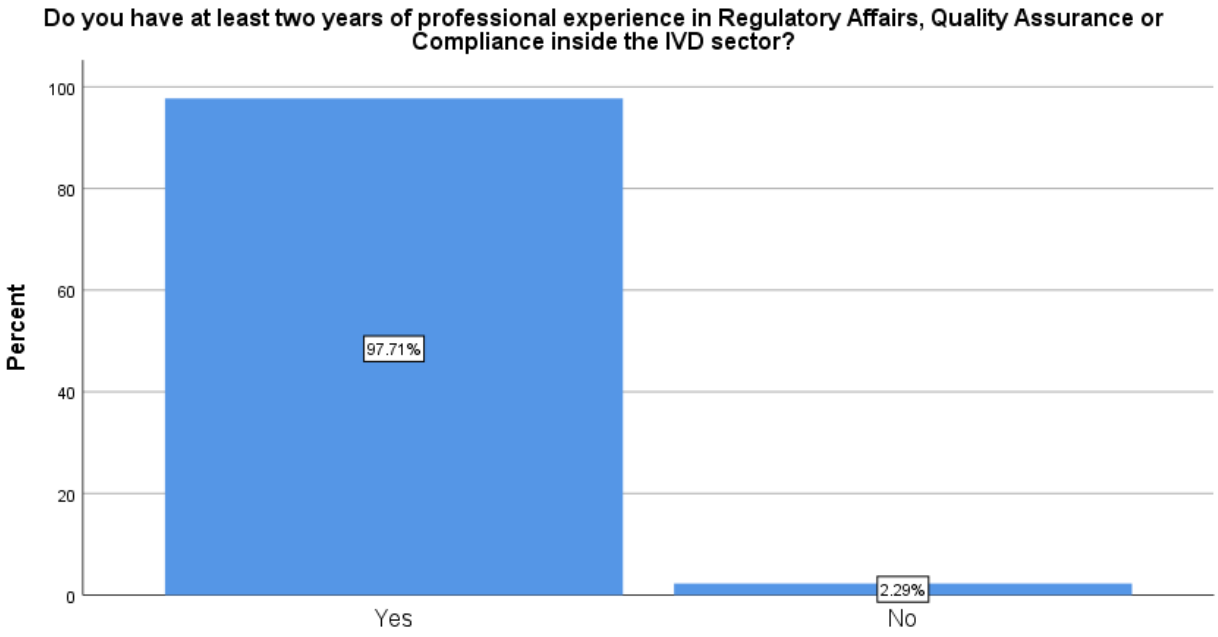

Figure 12: Professional Experience

During the analysis of the working status of the respondents, only 171 responses were considered. The most frequent occupancy was in Quality Assurance (35.09%), the next was Compliance Management (28.65%), Regulatory Affairs (25.15%), and Product Management (11.11%) (Figure 13). This combination makes available the views of both compliance-based and product-facing roles, which represent the diversity in the information gathered.

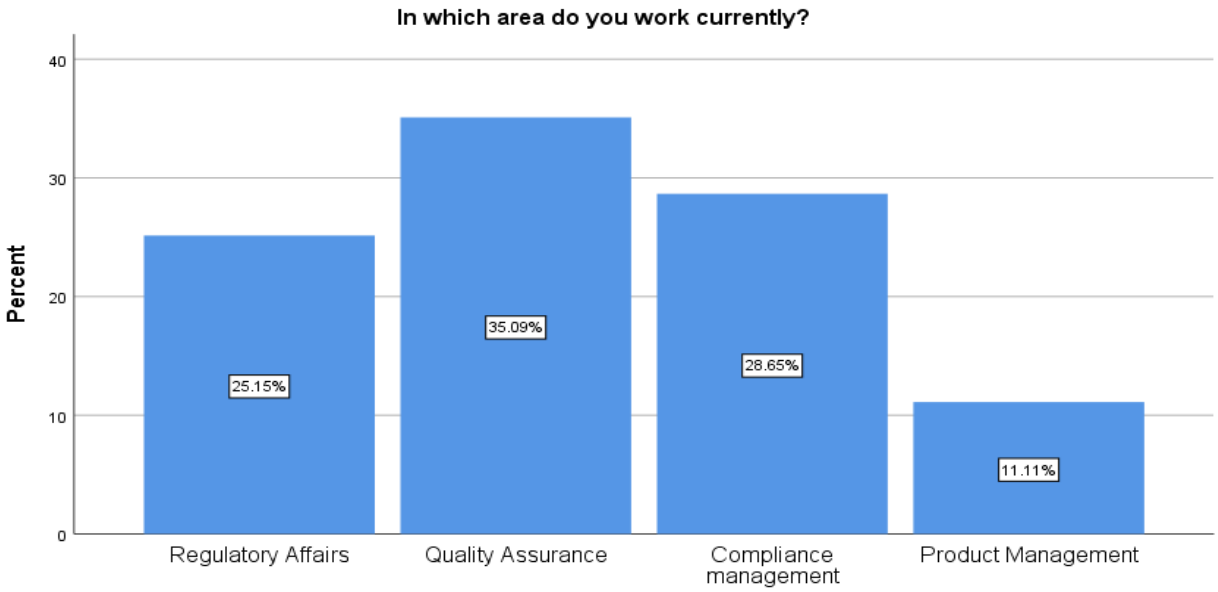

Figure 13: Current work designation

Question 4 asked respondents how many years of experience they had in the ranges of 2 – 5 years, 6 – 10 years, or 10+ years. In the case of the experience tenure analysis, it was identified that 73 respondents (42.69%) are in the 2-5 years industry experience bracket, 62 (36.26%) are in the 6-10 years bracket, and 36 (21.05%) are in the above 10 years bracket. Accordingly, the sample has most of the participants in the sample lie under the 2-5 year experience category (figure 14 and table 12).

Figure 14: Professional Experience

Table 12: Professional Experience in the IVD industry

How many years of professional experience do you have in the IVD industry?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2–5 years	73	40.1	42.7	42.7
	6–10 years	62	34.1	36.3	78.9
	More than 10 years	36	19.8	21.1	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Moreover, when asked what class of IVD kits their organisation manufactured, the majority of respondents answered that their company made different classes of manufacturing kits (question 5). In the manufactured classes of IVDs, Class C (36.84%) and Class B (26.90%) were dominant, with Class D respondents (22.81%) and Class A, respectively (13.45%) (Figure 15, Appendix A).

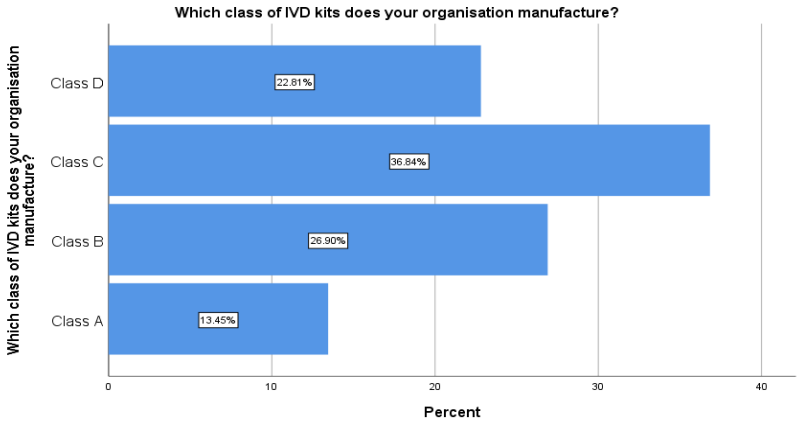

Figure 15: IVD Kits Manufacturing

Insofar as exportation to the EU is concerned, Class C (34.50%) and Class B (32.75%) are predominant, followed by Class D (22.22%) and Class A (10.53%) (Question 6). As per Figure 16, class C is the highest export medical device than class B and Class D. This analysis implies that the dataset can be effective in analysing the compliance requirements and challenges provided by IVDR.

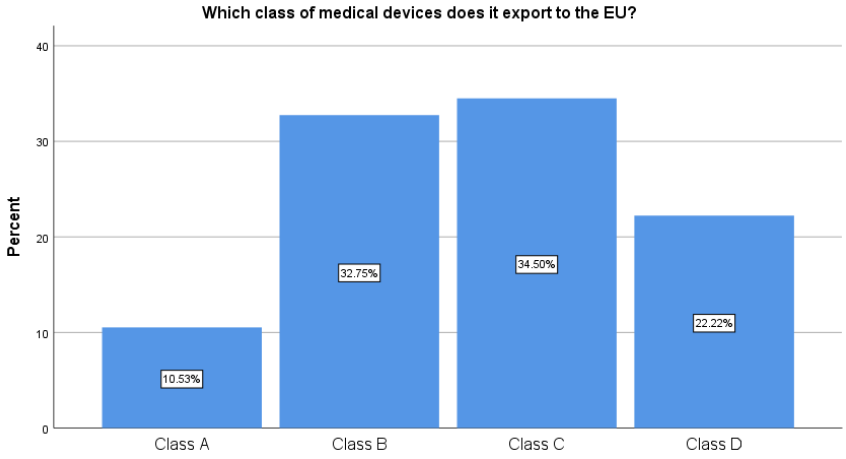

Figure 16: IVD Kits Export category-wise

ANOVA tests were applied. The findings demonstrated that the IVD kit classes did not differ significantly in readiness levels, $F(3,167) = 0.171$, $p = .916$, so the same perceptions occurred among Class A, B, C, and D makers (Appendix A). Nonetheless, a large difference was detected when considering the difficulty reported when accessing a Notified Body, $F(3,167) = 3.688$, $p = .013$. Since the classification of the organisations exporting Class C devices was significantly more difficult ($M = 2.86$) as compared to those exporting Class B devices ($M = 2.25$, $p = .019$), the post-hoc analysis was used. Therefore, in the above analysis, consider

screening variables, background sets, and an experienced and varied sample of respondents in terms of roles, tenure, product categories, and export profiles. This helps to analyse the participant's eligibility and profile significantly. These tested demographics justify the application of the inferential analysis, which assists in justifying the study objectives.

4.2.2 Organisational Readiness for IVDR Compliance

This section has focused on the analysis of the organisational preparedness towards EU IVDR 2017/746. During the survey question "**How equipped is your organisation for IVDR 2017/746 compliance?**" was asked to participants on a scale of fully compliant to not compliant. The analysis of the respondents who gave valid responses (n = 171) shows that the highest number classified their organisation as Partially Compliant (32.7%) and Fully Compliant (24%). Another 8.2% responded that their organisation was In Progress on their way to compliance, and another 35.1% declared they were Not Compliant (Appendix A). As per Figure 17, on average, organisations scored 2.27 with a Standard Deviation value of 0.921 on readiness, with 4 coded as "Not Compliant" and 1 coded as "Fully Compliant." Therefore, the analysis indicates that organisations were between partially compliant and in progress.

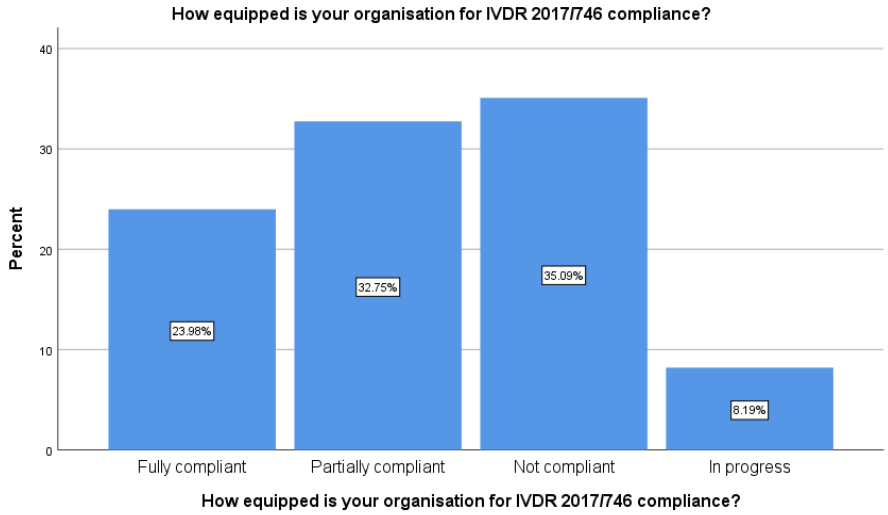

Figure 17: Level of preparedness of the organisation

Question 8 asked respondents whether their organisation had conducted any additional actions in response to IVDR. Regarding the measures taken, specifically, to prepare to be compliant, upskilling the current employees, using a form of training related to the IVDR (36.84%), was the highest-reported initiative according to Figure 18. It was then followed by the Reorganisation of internal teams or departments (19.30%), and increasing the allocation

of budget on compliance (9.63%). Other popular options included hiring outside consultants and hiring new staff in the regulatory or quality departments (34.50%) (Appendix A).

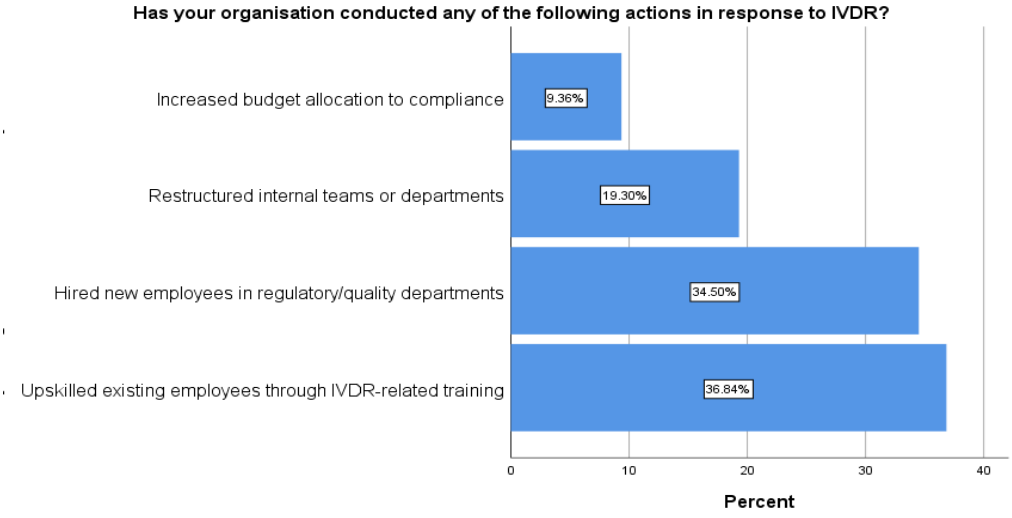

Figure 18: Organisation actions in response to IVDR

Question 9 focused on QMS and asked respondents whether a reorganisation was required to meet IVDR requirements. With regards to changes that the Quality Management System (QMS) required as part of IVDR, 25.15% of respondents (43 out of 171) indicated that their organisation was already in the process of regrouping its QMS to comply with IVDR, and 31% (53 out of 171) were still in the process of doing so (figure 19). A smaller percentage, 16.37% (28 out of 171), indicated that there was no such reorganisation that took place at all.

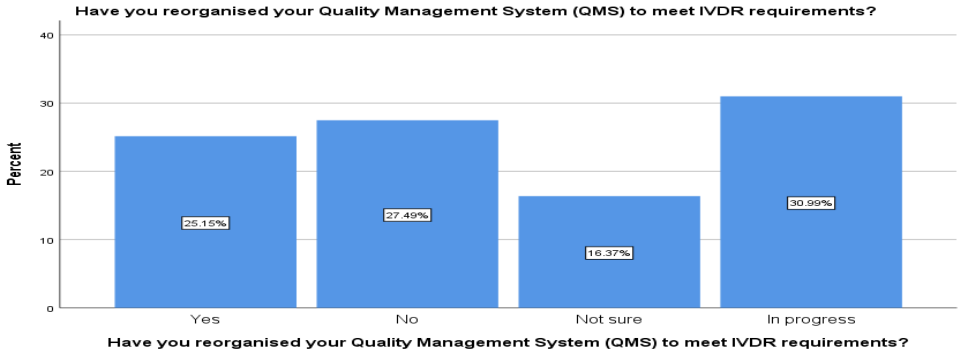

Figure 19: Reorganisation of QMS to meet IVDR

Furthermore, question 10, "What new reports or studies were required during the transition from IVDD to IVDR?" was considered, which helps to identify which document is mostly required for the transition. As per Figure 20, among newer documentation needs, the Performance Evaluation Report (PER) (38.60%) was the most frequently required document

during transition, followed by Risk Management File (14.04%) and Post-Market Performance Follow-Up (PMPF) (23.39%). Moreover, 23.98% of the respondents demanded clinical performance studies (Appendix A).

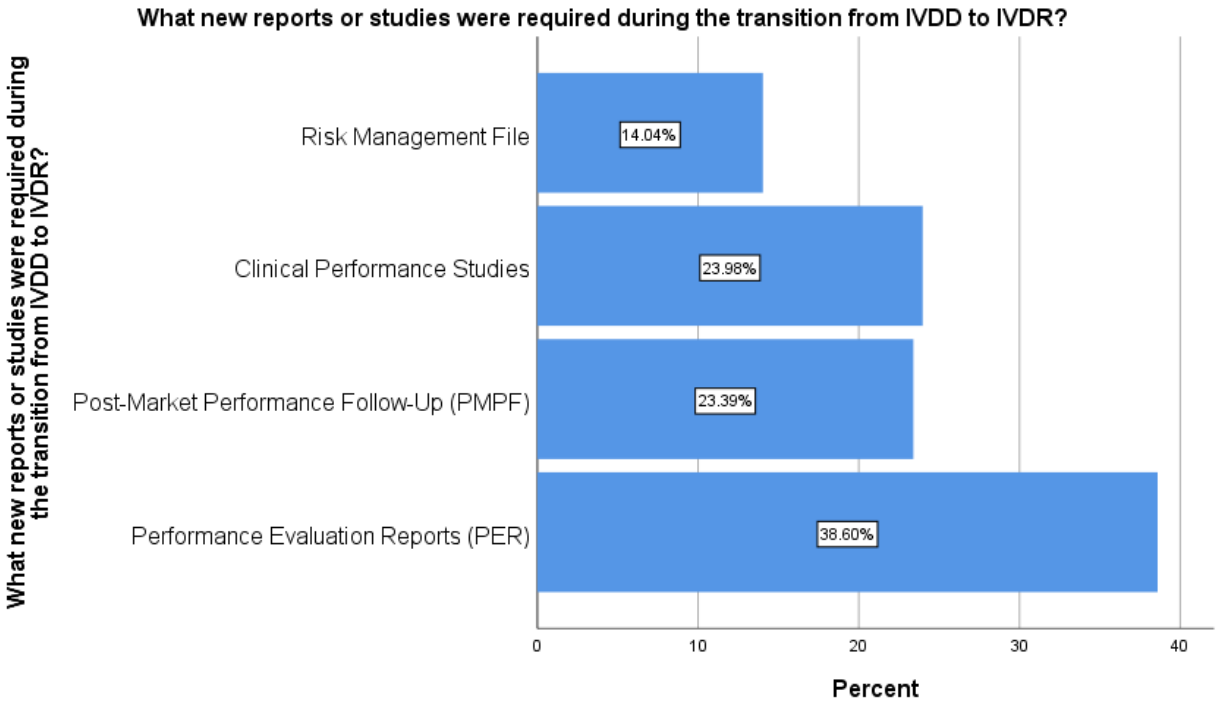

Figure 20: Report required in Transition from IVDD to IVDR

During the analysis of the challenges, question 11 was asked to participants, with which focus on identifying which area they thought posed the highest challenge during the transition from IVDD to IVDR. The commonly mentioned top single challenge during the transition was NB delays (39.18%, 67 out of 171), Documentation complexity (17.54%, 30 out of 171), Internal resource limitations (20.47%, 35 out of 171), and then Clinical evaluation (22.81%, 39 out of 171). Perceptions of organisational readiness to comply with IVDR 2017/746 were examined to reveal the existence of differences in those depending on the various characteristics of organisations (Figure 21).

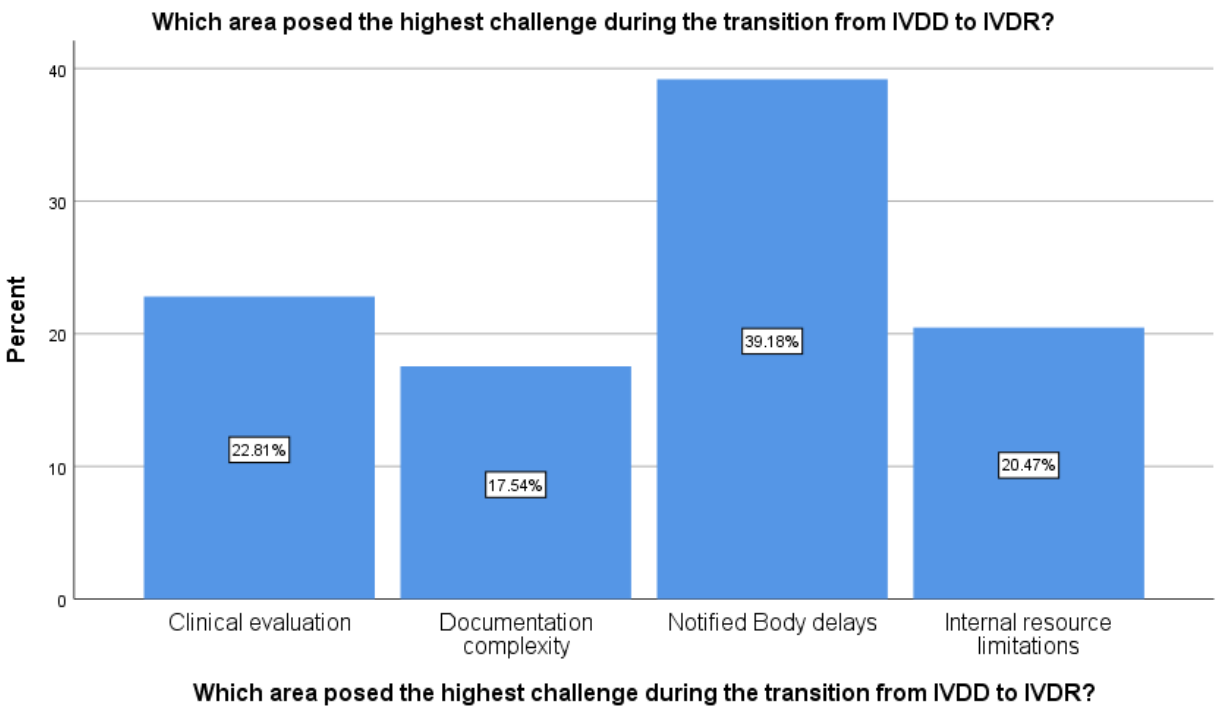

Figure 21: Challenges during the transition from IVDD to IVDR

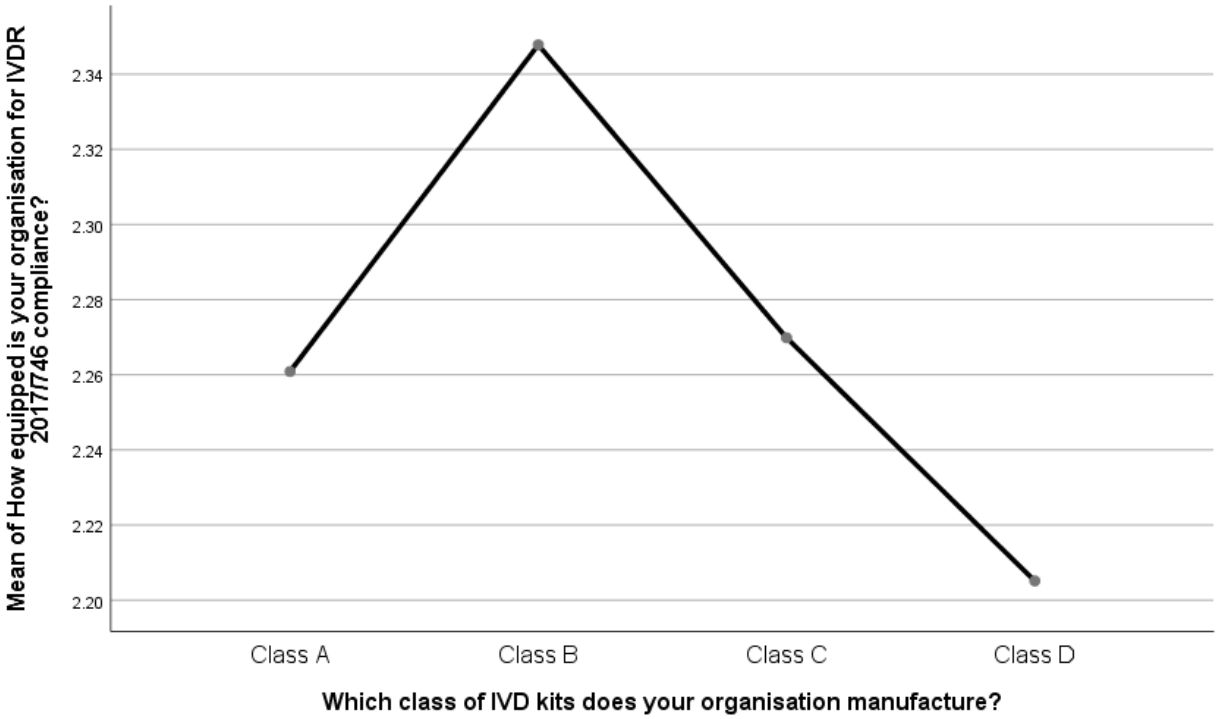

Figure 22: IVD Kits manufacturing

The effectiveness of communication about the IVDR transition during the transition also differed considerably over the current work areas, F (3,167) = 5.726 p = .001, with the

respondents in Regulatory Affairs (M = 3.23) and Product Management (M = 3.32) indicating that the communication was more effective compared to the Quality Assurance (M = 2.40) (Appendix A). The findings indicate that the readiness perceptions do not vary across product categories, some professional positions, and products with increased risk hold more problems and varied experience in the realm of effective communication.

4.2.3 Impact of Organisational Factors on Readiness

To identify the impact of the organisational factor on readiness, the correlation and regression analyses were used. These help to examine the connection between organisational variables and operational variables and the general viability of meeting the demands of the IVDR. Pearson correlation coefficients were estimated where readiness score (coded to level 4 = Not Compliant to level 1 = Fully Compliant) was used as the dependent variable, whereas important organisational variables were used as continuous or scale-coded independent variables. The readiness of IVDR compliance is very weakly, non-significantly correlated with each of the predictors: difficulty with accessing a Notified Body (NB) ($r = -.148$, $p = .054$), effectiveness of communication ($r = -.056$, $p = .463$), impact on the IVDR of cost ($r = .036$, $p = .636$) and time spent on CE-marking ($r = .075$, $p = .331$) (Appendix A). The effects are insignificant and fail to achieve a $p < .05$, and readiness is not a linear construct with these variables at the bivariate level within the present sample (Table 13).

Table 13: Correlation analysis

Correlations

		How equipped is your organisation for IVDR 2017/746 compliance?	Rate the level of difficulty in accessing a Notified Body for IVDR certification.	How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	To what extent has IVDR impacted regulatory costs for your organisation?	What is the estimated average time taken to get CE marking under IVDR?
How equipped is your organisation for IVDR 2017/746 compliance?	Pearson Correlation	1	-.148	-.056	.036	.075
	Sig. (2-tailed)		.054	.463	.636	.331
	N	171	171	171	171	171
Rate the level of difficulty in accessing a Notified Body for IVDR certification.	Pearson Correlation	-.148	1	.335**	.213**	.063
	Sig. (2-tailed)	.054		.000	.005	.412
	N	171	171	171	171	171
How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	Pearson Correlation	-.056	.335**	1	.021	-.151*
	Sig. (2-tailed)	.463	.000		.788	.049
	N	171	171	171	171	171
To what extent has IVDR impacted regulatory costs for your organisation?	Pearson Correlation	.036	.213**	.021	1	-.054
	Sig. (2-tailed)	.636	.005	.788		.483
	N	171	171	171	171	171
What is the estimated average time taken to get CE marking under IVDR?	Pearson Correlation	.075	.063	-.151*	-.054	1
	Sig. (2-tailed)	.331	.412	.049	.483	
	N	171	171	171	171	171

However, there exist significant correlations involving the predictors themselves: During the correlation, those aspects are considered significant whose p-value is less than 0.05, and those aspects are considered non-significant whose p-value is greater than 0.05. In the case of a non-significant case, reject the null hypothesis. The difficulty of access to NB is positively correlated with communication ($r = .335$, $p < .001$), and against cost impact ($r = 0.213$, $p = .005$), and communication is loosely but statistically significantly correlated against CE-marking time ($r = -.151$, $p = .049$). Therefore, these show little to moderate connections among operational issues surrounding the IVDR transition (Appendix A). These factors were analysed together as the combined predictive power over readiness was done through multiple linear regression.

Table 14: Regression analysis

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.187[a]	.035	.012	.915	.035	1.496	4	166	.206

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.013	4	1.253	1.496	.206[b]
	Residual	139.069	166	.838		
	Total	144.082	170			

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	2.164	.351		6.173	.000
	Rate the level of difficulty in accessing a Notified Body for IVDR certification.	-.141	.067	-.175	-2.091	.038
	How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	.011	.063	.015	.176	.860
	To what extent has IVDR impacted regulatory costs for your organisation?	.064	.064	.078	.999	.319
	What is the estimated average time taken to get CE marking under IVDR?	.101	.085	.092	1.183	.239

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.84	2.78	2.27	.172	171
Residual	-1.592	1.896	.000	.904	171
Std. Predicted Value	-2.506	2.937	.000	1.000	171
Std. Residual	-1.740	2.071	.000	.988	171

When the 4 predictors of readiness communicate, the NB access difficulty, communication, and cost impact, and CE-marking time are taken into consideration simultaneously, the overall model is not significant. In addition, the model provides the value of .187 R value .035 R2 value, adjusted R2 was .012, F(4,166) was 1.496, and p = .206. These suggest a very low explained variance (Appendix A).

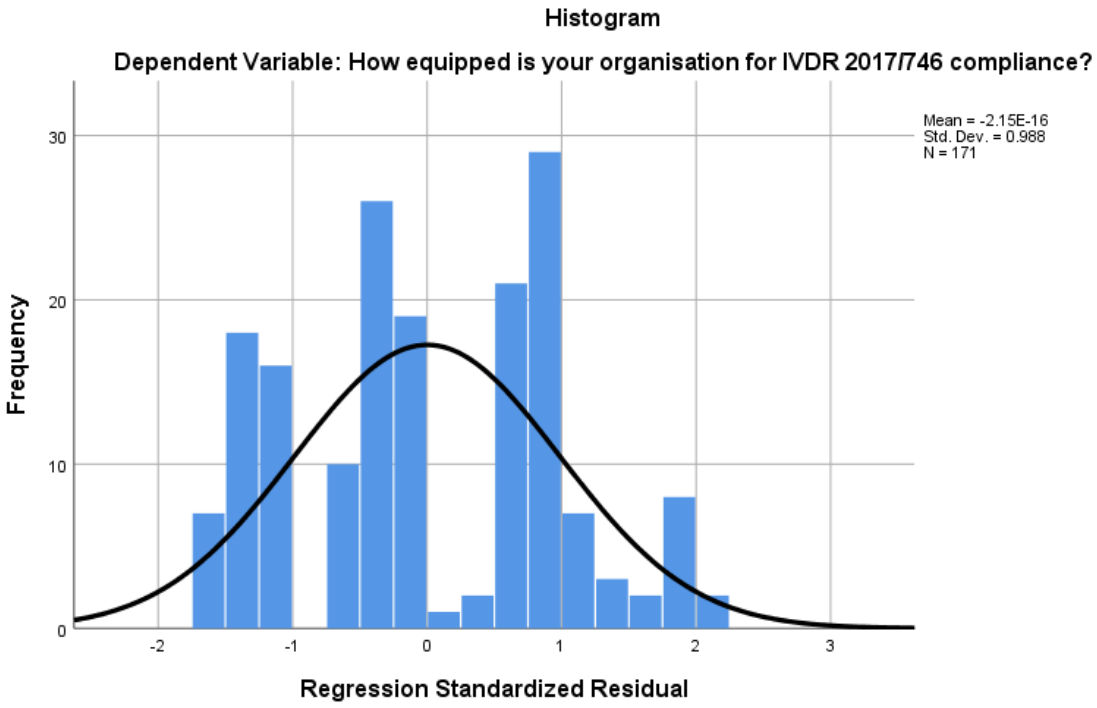

Figure 23: Histogram analysis of the equipped

In this non-significant model, one of the coefficients is individually significant: more NB access difficulty is associated with less readiness because B was -.141, SE was 067, B was -.175, t was -2.091, and p was .038. The remaining predictors are found not to be significant: communication (B =.011, p =.860), cost impact (B =.064, p =.319), CE-marking time (B =.101, p =.239). Such coefficients are to be perceived tentatively because of the non-significance of the overall model.

NB access difficulty was revealed as a strong predictor in this model (Appendix A). It shows that access problems to NB entail lower preparedness to comply with IVDR. Nonetheless, communication (p = .860), cost impact (p = .319), and CE-marking time (p = .239) are other predictors that could not be statistically significant (Appendix A). Thus, NB access difficulty is the only indicator that presents a meaningful correlation with readiness. In addition, it indicates that the issues concerning NB access can be vital during preparation, whereas the other variables did not demonstrate a robust measurable impact in this model.

These results point to the fact that preparation for the IVDR compliance rests on some enabling and limiting aspects. Communication comes up as a major success factor, and

procedural delay and regulation bottlenecks, especially in the case of Notified Bodies and the CE marking schedules, negate the preparation efforts.

4.2.4 Analyse the importance of Compliance Challenges and Documentation Updates

The descriptive and inferential analyses were conducted to evaluate compliance challenges that organisations experienced during the transition from the IVDD to the IVDR. Respondents referred to many types of updates in documentation, procedural blockers, and regulatory bottlenecks involved in the process of transition. In response to question 13, regarding the key documents that were changed in terms of IVDR requirements (N = 171), the most common was the Technical Documentation (21.05%, 36), followed by the PER (31.58%, 54) and the PMPF reports (36.26%, 62) as stated in Figure 24. Of the respondents, 11.11% (19) described an update to Clinical Evidence Documentation and mentioned the lack of any applicable documentation update (Appendix A). These findings imply that most organisations have done considerable technical file revisions to comply with IVDR, especially in the areas of performance evaluation and post-market surveillance.

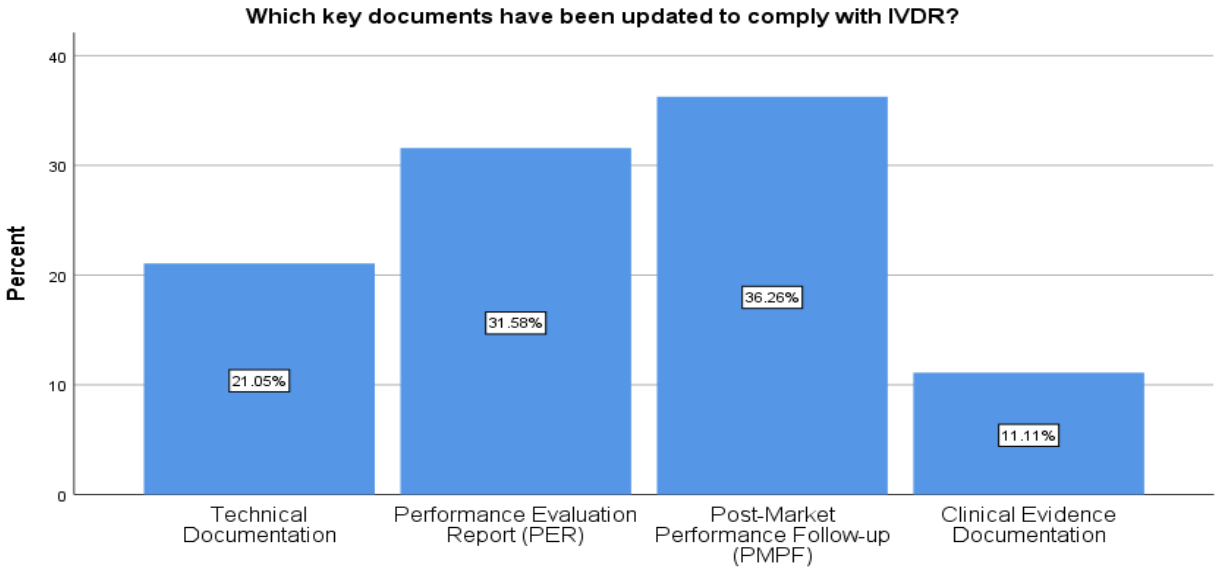

Figure 24: Key Documents in IVDR

Difficulties of contacting an NB were examined as well with the help of question 14. The degree of difficulty was rated on a four-point scale of difficulty (1 = Very Easy to 4 =Very Difficult). This process was rated by the largest group as Difficult (22.22%), with another rank in the ratings being Very Difficult (20.47%). 32.16% respondents believed that it was Somewhat Easy, and only 21.64% described the process to be Very Easy, and 3.51% had not

attempted to achieve certification stated in Figure 25. With a mean difficulty score of 2.52 (SD = 1.144), the overall average difficulty in participating with the Notified Bodies within the new regulation was set at a high level (Appendix A).

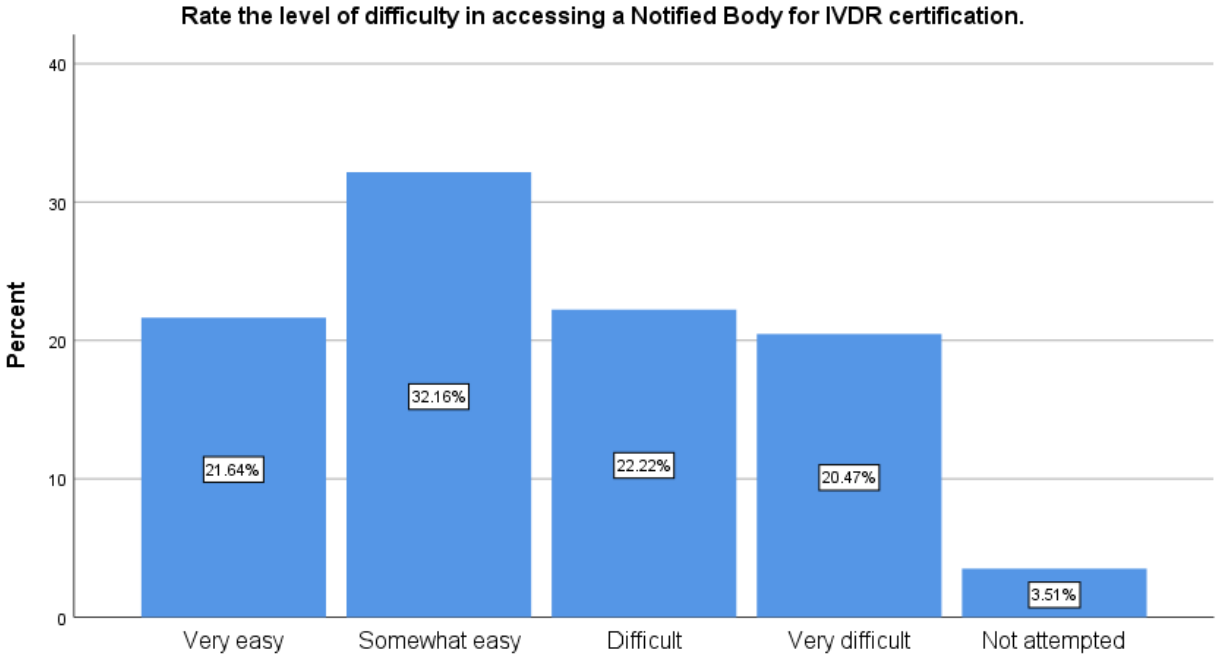

Figure 25: Level of difficulty

The reorganisation of QMS was significantly related to the current work area (x2(9, N=171 = 24.244, p =.004), whereas its effect was small to moderate in size (V = .217) in Figure 26. This implies that the potentials of reporting QMS changes differ in Regulatory Affairs, Quality Assurance, Compliance Management, and Product Management. In comparison, there was no meaningful relationship between QMS reorganisation and device class exported to the EU (2 (9) = 6.204, p = .719; V = .110) or IVD class produced (2 (9) = 8.143, p = .520; V = .126). On the whole, these results indicate that the QMS adaptations bear a greater relationship to internal functional positioning rather than the external market class mix of an organisation (Appendix A).

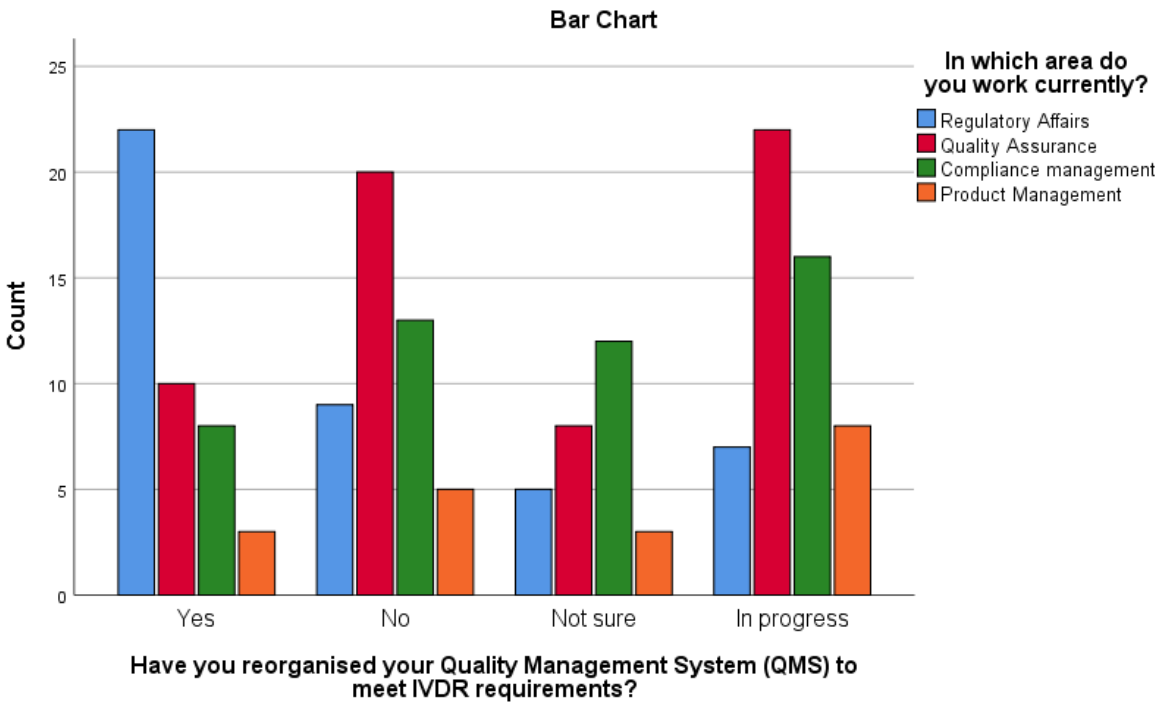

Figure 26: QMS to IVDR requirements

Furthermore, utilising outside consultancy to facilitate IVDR compliance was strongly linked to work area (2 (6, N = 171) = 15.438, p = .017; Cramer V = .212). This suggests a difference in dependence on external expert advice by functions and, perhaps, a difference in documentation, evaluation, or cost audit demands. Nevertheless, there were no meaningful correlations with the device class exported (2(6) = 5.473, p = .485; V = .127) or the IVD class manufactured (2(6) = 8.820, p = .184; V = .161). Therefore, it would seem that organisational role demands influence the use of consultancy rather than the profile of the risk classes of products (Appendix A).

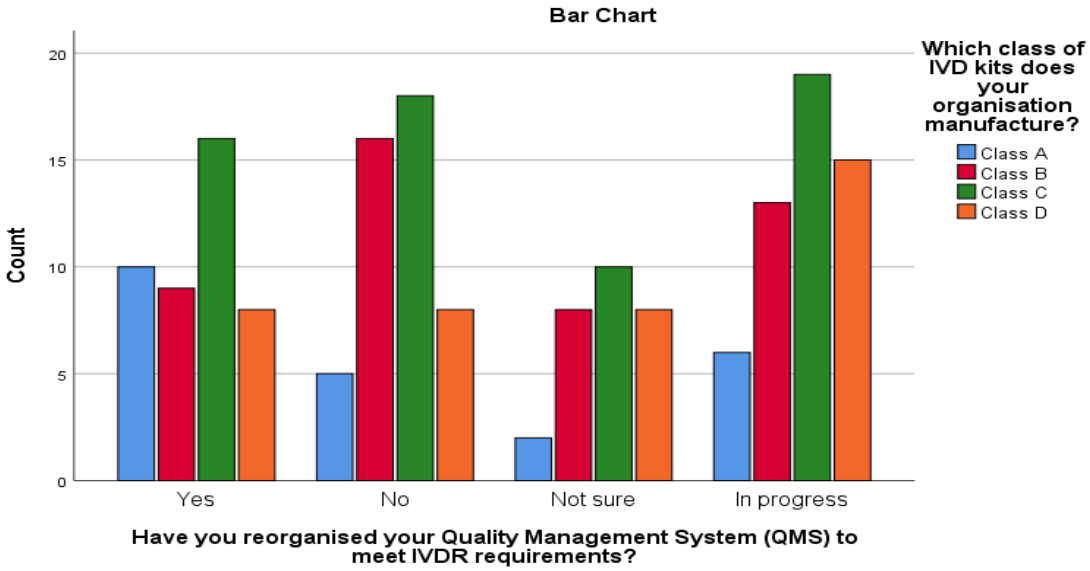

Figure 27: QMS to IVDR requirements

In addition, past exposure to delay having CE marking was found to be related to the current work area significantly (2 (6, N = 171) = 13.644, p =.034; Cramer 2 (.200), which shows that past delay exposure was observed differently across the functional group. Conversely, there was no substantial relationship between device class exported (x 2 (6) = 2.156, p = .905; V =.079). The relationship between the IVD class manufactured was approaching significance without reaching the 5 % level (V = .181) (Appendix A). Taken together, these findings suggest that perceived certification delays might be more of a factor of where an organisation sits in the respondent group rather than product category alone.

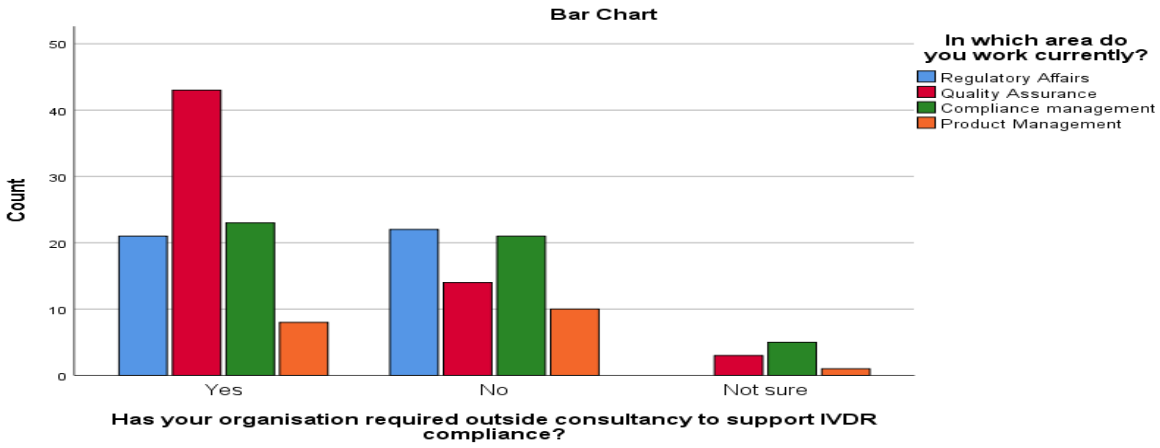

Figure 28: Outside Consultancy

Therefore, the chi-square tests are relatively unifying in demonstrating functional role as the most illuminating differentiator of organisational action (QMS change, consultancy) and outcome (CE-mark delay), whereas the product class variables (manufactured/exported) display it either as null or just on the borderline of significance.

4.2.5 Analysis of Certification Outcomes and Market Access

This study focuses on the analysis of the effects of the introduction of IVDR on access to the market and deadlines of acquisition of certification, for the CE marking procedures and the delays therein, with the help of question 17. Responding to whether they had encountered delays getting CE marking under IVDR, 40.94% marked Yes, 47.37% No, and 11.70% Not Applicable (figure 29). Of those reporting delays, qualitative observations identified the reasons to include the length of Notified Body review, repetitive document requests, and closer examination of technical files.

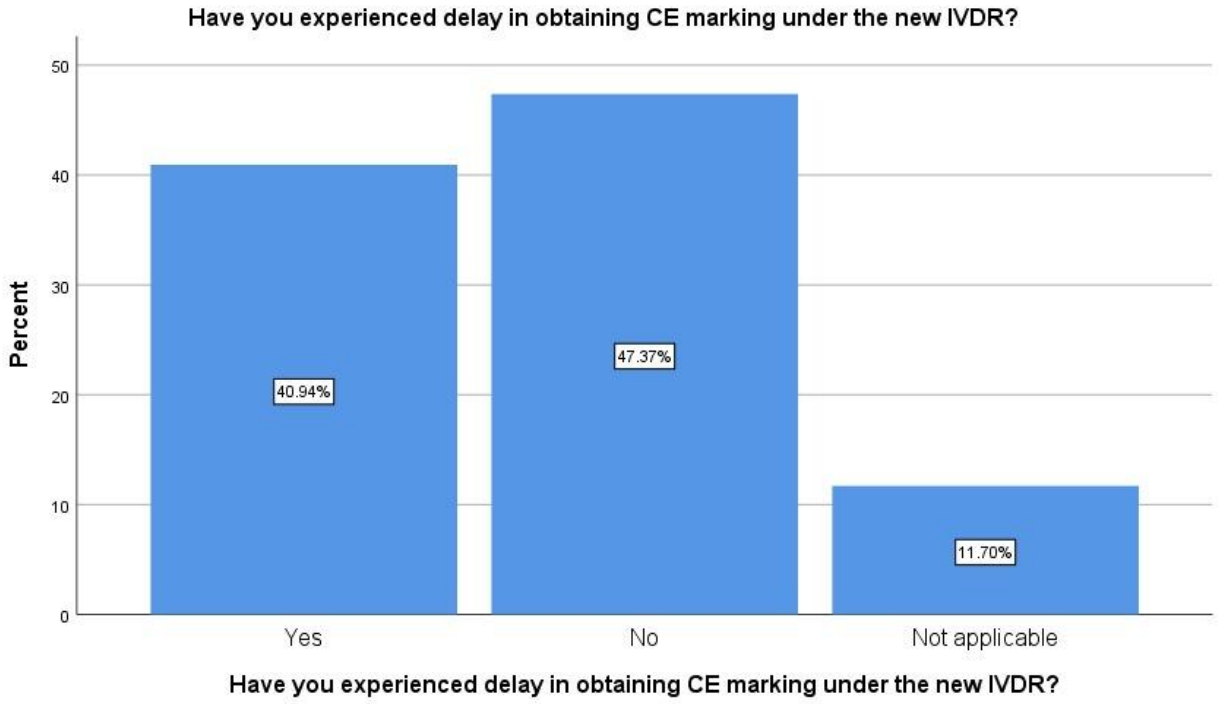

Figure 29: Delay in obtaining CE marking in IVDR

The mean duration of acquisition of CE marking in the environment of IVDR was also measured with the help of question 18. The largest duration cited was 6-12 months (46.78%), and the second highest duration was over 12 months (28.65%) (Figure 30). The Less than 6 months category only demonstrated 15.20% with certification, and 9.36% responded that no

CE marking had yet been achieved (Appendix A). This allocation indicates that most of the organisations are experiencing fairly long certification periods compared to the previous IVDD procedures.

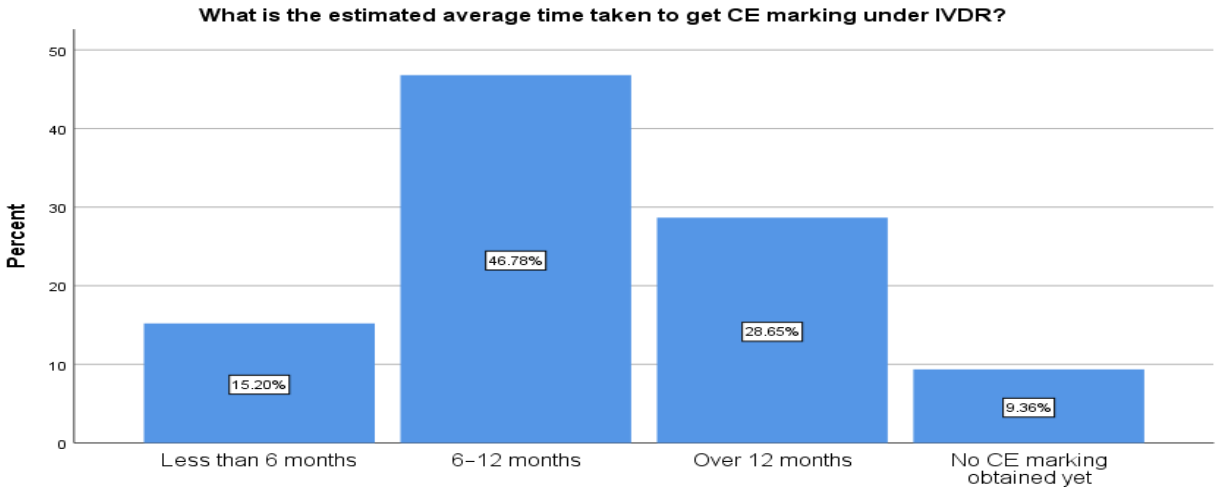

Figure 30: Estimated Average Time

Moreover, the question "Compared to your organisation's past experience with CE marking under the IVDD, how you would describe this timeframe?" was considered. In comparison of these timelines with the previous experience of the organisations under IVDD performing CE marking, approximately 46.20% have reported that the process was slower than that of IVDD, 21.05% were about the same, and 15.20% have indicated that it was Faster. Another 17.54% said Not Sure or No Prior Experience (figure 31).

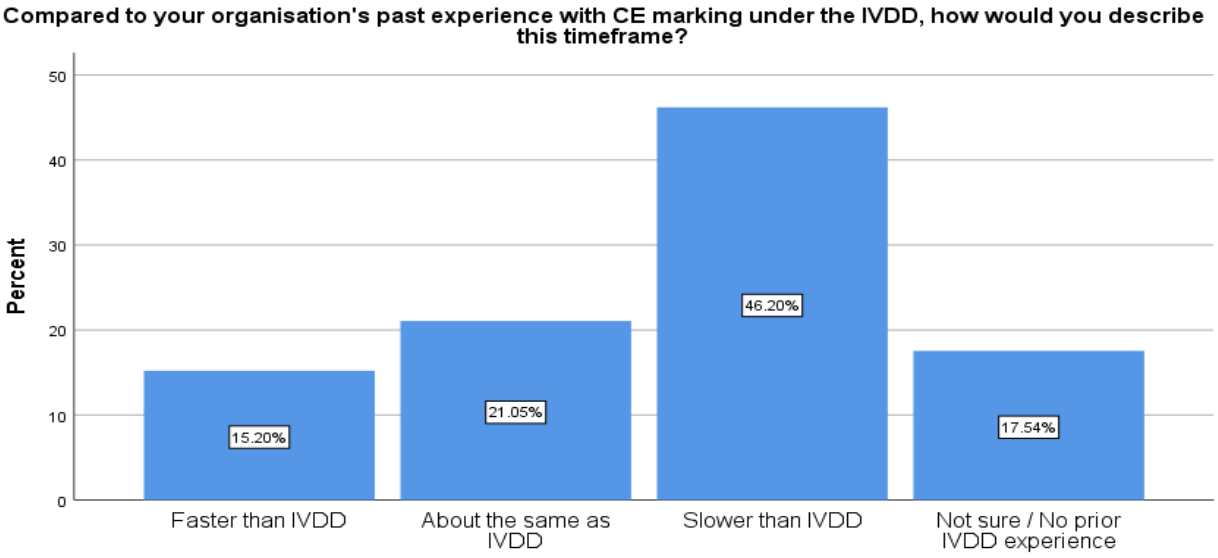

Figure 31: Past Experience with CE marking

The key market-access outcomes described under IVDR (CE-mark delays) and associated process decisions found to vary with relevant perceptions (use of outside consultancy) were investigated using independent-samples t-tests.

Table 15: Indian In Vitro Diagnostic (IVD) manufacturing industry

Group Statistics

	Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?	N	Mean	Std. Deviation	Std. Error Mean
How equipped is your organisation for IVDR 2017/746 compliance?	0	0[a]	.	.	.
	Yes	171	2.27	.921	.070

The test of comparing the preparedness to IVDR compliance with the current employment within the market in the Indian IVD manufacturing industry was impossible to be conducted as there were no valid cases in one of the groupings. In the output, the "No" (or "0") category is of N = 0, resulting in be in-calculable value stated in table 16. In practice, this implies that this sample will only have the respondents who have worked in the sector, and there is no possibility of between-group inference for this comparison.

Table 16: Currently working in the Indian In-Vitro Diagnostic (IVD) manufacturing

Group Statistics

	Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?	N	Mean	Std. Deviation	Std. Error Mean
How equipped is your organisation for IVDR 2017/746 compliance?	Yes	171	2.27	.921	.070
	No	0[a]	.	.	.

Furthermore, a comparison of access to Notified Body (NB) difficulty between the organisations that involved the usage of outside consultancy or not. The values of means were 2.47 (SD = 1.13; n = 95) ("Yes" or consultancy) and 2.66 (SD = 1.188; n = 67) ("No"). The test by Levene testified towards homogeneity of variances (F = 0.505, p = .478). The t-test result was insignificant (t(160) = 0.995, p = .321; mean difference = -0.183, 95% CI [-0.546, 0.180]) stated in Table 17. Therefore, the importance of Consultants Company, in the context of this data, does not imply the possibility of more convenient access to NB on the bivariate level.

Table 17: Organisation required outside consultancy to support IVDR compliance

Group Statistics

	Has your organisation required outside consultancy to support IVDR compliance?	N	Mean	Std. Deviation	Std. Error Mean
Rate the level of difficulty in accessing a Notified Body for IVDR certification.	Yes	95	2.47	1.128	.116
	No	67	2.66	1.188	.145

Moreover, during the analysis compared the effectiveness of communication among organisations that suffered delays during the implementation of CE-marking policies and organisations that did not was compared. Means were 2.79 (SD = 1.215; n = 70) in the group where the question was Yes and 2.80 (SD = 1.18; n = 81) when it was No. Levene F = 0.464, p = .497, homogeneous variances stated in table 18. The t-test was insignificant (t(149) = -0.086, p = 0.932; mean difference = -0.017, 95% = [-0.402, 0.368]) (Appendix A). This implies that communication ratings are basically the same, having or not experienced a delay.

Table 18: Experienced delay in obtaining CE marking under the new IVDR

Group Statistics

	Have you experienced a delay in obtaining CE marking under the new IVDR?	N	Mean	Std. Deviation	Std. Error Mean
How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	Yes	70	2.79	1.215	.145
	No	81	2.80	1.177	.131

Therefore, the t-tests do not reveal group differences that are statistically significant in regard to the following contrasts, such as consultancy vs NB difficulty and delay vs communication. Additionally, there is no employment status of readiness that could be tested because of a vacuous comparison group. Substantively, the results indicate that on the basis of these pairwise comparisons alone, the reported CE-mark delays and consultancy use do not translate into reported results in distinct perceptions.

4.2.6 Perceptions of IVDR Impact and Recommendations

To measure the views of the stakeholders regarding the regulatory change, the respondents were asked question 23 on whether they agreed with the statement that EU IVDR 2017/746

makes products safer and the market more reliable. Most of the valid responses (N = 171) were positive: 32.16% Strongly Agreed, and 43.27 % Agreed, as per Figure 32. Furthermore, 18.71% disagreed, and 5.85% strongly disagreed (Appendix A). This distribution implies that over four out of five participants have a positive view of the effect of IVDR on safety and reliability.

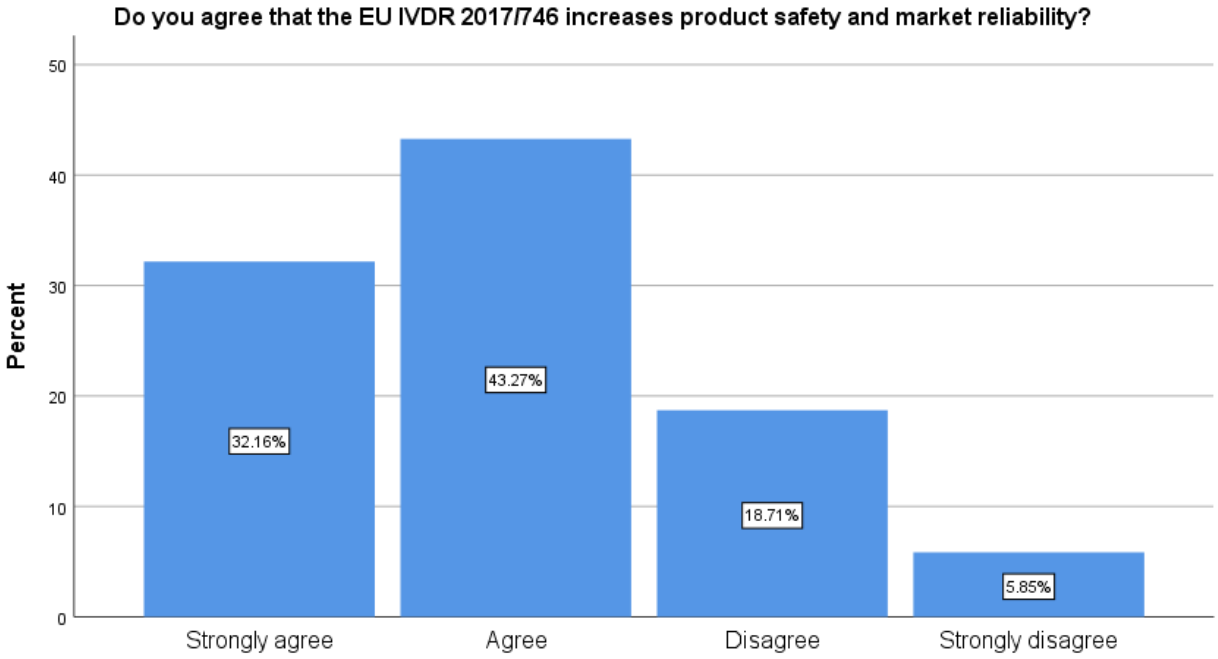

Figure 32: Product Safety

The analysis of the perceptions of the respondents was carried out through a one-way ANOVA to identify the differences among different perceptions in their organisational and professional characteristics. The understanding of the analysis involved the question of whether the organisational preparedness for the IVDR 2017/746 compliance differed by the type of IVD kits produced. The findings showed that there was no significant observed difference between the groups, F (3,167) = 0.171, p = 0.916, which implies that the classes of manufacturers A, B, C, and D companies had the same perception of readiness levels (Appendix A). With a p-value of 0.916, reject the null hypothesis; therefore, there is no statistical significance (Table 19).

Table 19: Organisational preparedness for the IVDR 2017/746

ANOVA

How equipped is your organisation for IVDR 2017/746 compliance?

	Sum of Squares	df	Mean Square	F	Sig.

Between Groups	.441	3	.147	.171	.916
Within Groups	143.641	167	.860		
Total	144.082	170			

The analysis was then done on whether the difficulty in accessing a Notified Body was differently reported according to the class of medical devices being exported to the EU. There was a large difference, F (3,167) = 3.688, p = .013. With Tukey post-hoc comparisons, it was revealed that organisations exporting Class C devices indicated a much harder time (M = 2.86) compared to organisations exporting Class B devices (M = 2.25, p = .019) (Appendix A).

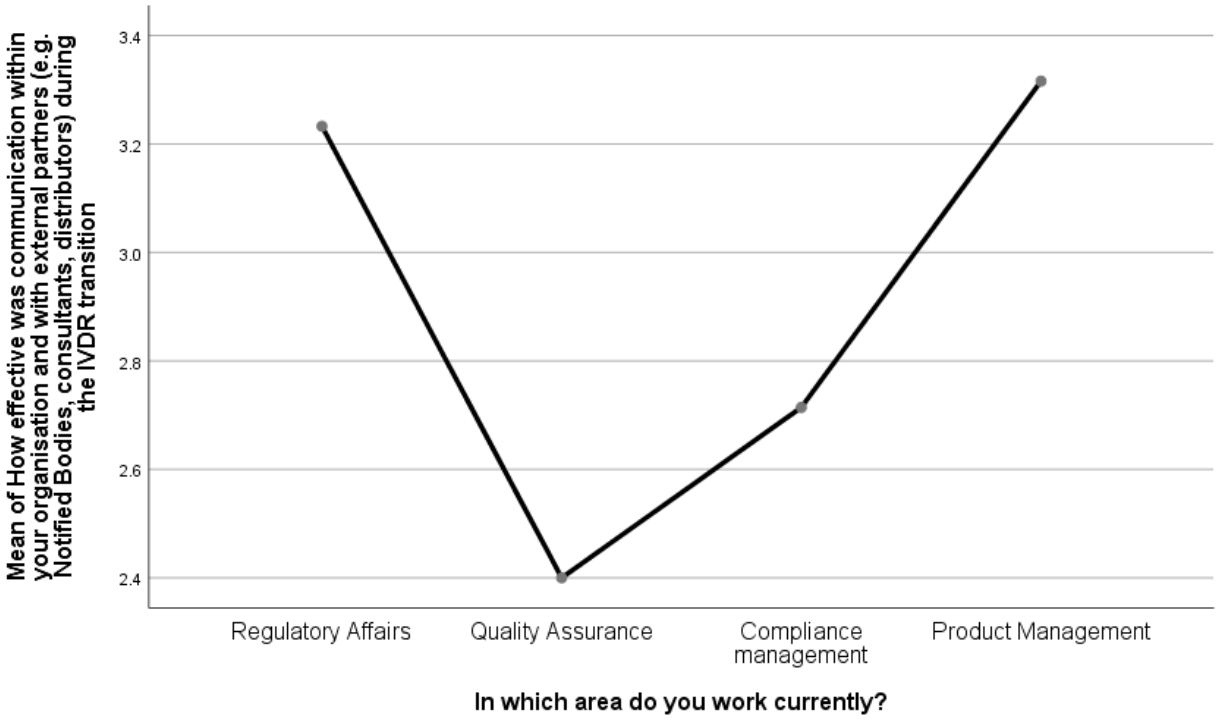

Figure 33: Current area of work

All other differences were not significant. Furthermore, the current areas of work were compared in terms of the effectiveness of communication in the course of the transition of the IVDR. The ANOVA showed that there was a substantial impact, where F (3,167) = 5.726, p = .001. Tukey post-hoc tests indicated that the respondents in Regulatory Affairs (M = 3.23) and Product Management (M = 3.32) felt more effective communication compared to the respondents of the Quality Assurance (M = 2.40), with p values of .002 and .016, respectively. Other group comparisons did not turn out statistically significant (Appendix A). Therefore, the results indicate that the accessibility of Notified Bodies may be more severe

in the case of exporting organisations producing devices with a higher risk level, and the effectiveness of communication quite possibly relies on the professional role of the respondent, with Regulatory Affairs and Product Management reporting more positive interactions than Quality Assurance.

4.3 Qualitative analysis

During the qualitative analysis, the thematic analysis procedure has been considered, which helps to form the common themes based on the research objective and helps to evaluate the collected qualitative information significantly. A thematic analysis was used in the qualitative analysis. Initially, responses were read to become familiar, and key phrases were marked using open coding. These codes were then grouped into categories, which were further summarised into broad themes according to the objectives of the study. This organised procedure made sure that the themes were patterned and relatable. Furthermore, the following table 20 provides information about the themes that helped to evaluate the collected information.

Table 20: Themes development

Sr. No	Theme	Keywords
1	Organisational Strategies for IVDR Compliance	QMS updates, training, restructuring, performance evaluation reports, clinical performance studies, and consultancy
2	Challenges Faced During IVDR Transition	Documentation complexity, Notified Body delays, internal resource limitations, cost increase, and CE marking delays.
3	Perceived Benefits and Recommendations	Product safety, market reliability, regulatory support needs, and readiness improvement

4.3.1 Organisational Strategies for IVDR Compliance

As per the analysis, it is identified that a variety of organisational measures have been implemented to meet the compliance with IVDR 2017/746. Some companies have restructured their Quality Management Systems (QMS) to comply with the regulatory needs, and this is normally done through an organised revision of the technical documentation, as well as a more stringent internal revision mechanism. One of the popular measures has been ensuring that current employees receive training on IVDR in particular, so that they can meet new performance assessment requirements as well as risk management requirements. Certain organisations have embarked on recruiting new professionals in the field of regulation or

quality to reinforce expertise internally, whereas others have engaged in an external consultancy to deal with the complexities in making the transition. Furthermore, introduced compliance activities regularly have been referred to as Performance Evaluation Reports (PER) and Post-Market Performance Follow-Up (PMPF) studies, as well as clinical performance studies. These strategies show that Indian IVD manufacturers are trying on their own accord to not only build internal capacities to meet EU requirements, but are also seeking specific external assistance to achieve the same. These multi-pronged strategies are not marks of adaptiveness, but also factors that point to an understanding of compliance as both a procedural and technical endowment. Therefore, areas of interest among the respondents are structured planning, capacity building, and specialised documentation procedures to establish timely certification in the IVDR framework.

4.3.2 Challenges Faced During IVDR Transition

This analysis focused on the analysis of challenges that occur during the transition to IVDR compliance. Complexity of documentation is one of the major challenges, especially the fact that technical files and clinical evidence reports have to be more detailed. Delays in appointments with Notified Bodies are reported by many of the respondents, which frequently extend the certification cycles. Internal resource constraints, such as the lack of well-trained personnel and an inadequate budgetary allocation to various functions concerning compliance, were also singled out as major obstacles. The regulatory costs have risen in most organisations; most have either faced a rise in costs classified as a major cost rise or a minor cost rise. Other repeated problems were CE marking delays, as timelines frequently exceeded 12 months in the case of the IVDD process. Such delays have at times slowed access to the market and the launch plans of products. The bottlenecks in regulation, pressure on workload, and economic stress are a complex problem in the context of Indian IVD manufacturers. In addition, these obstacles are not only operational but strategic as well, necessitating the adjustment of companies that struggle with the shift in timeframes, resources, and internal mechanisms. The analysis suggests that unless these challenges are resolved with better infrastructures and simplified communication between regulators, compliance will continue to be a continuous aspect for most organisations operating under the IVDR environment.

4.3.3 Perceived Benefits and Recommendations

Regardless of the challenges encountered, a high number of respondents consented to the idea that IVDR delivers as regards product safety and market trustworthiness. The regulation can be seen as stimulating better clinical performance assessment, enhanced risk management, and enhanced post-market surveillance mechanisms. The participants represent that these improvements are beneficial to patients eventually and increase their trust in the products used in diagnosis. However, they also stress that regulatory assistance is required to aid that compliance. They are proposed to be achieved through the addition of clear guidance documents, accelerated Notified Body procedures, and monetary incentives and subsidies aimed at small manufacturers. Some respondents suggest the enhancement of industry regulator links in order to have a seamless transition and minimise delays. They observe that readiness to comply can be enhanced by early adoption of requirements of performance evaluation, active training programmes, and constant improvement of the processes within QMS. Moreover, though IVDR requires much operational and financial effort also drives the industry to advance in the quality and reliability of goods. Therefore, increasing competitiveness in the EU market, this two-pronged vision denotes a more accurate perception of direct compliance with the regulatory demands.

4.4 Discussion

4.4.1 Analysis of Regulatory Barriers to IVDR Compliance

The regulatory barriers are the greatest drawback on the way to the IVDR compliance and help to justify the objective of the study to analyse the external challenges that organisations experience in the process of switching between the IVDD and the IVDR. Furthermore, the qualitative and quantitative findings represent that the inadequacy of the Notified Body (NB) capacity, higher financial pressure, the complexity of documentation, and technological weaknesses are the major barriers. As per the quantitative analysis, it is identified that NB access was a statistically significant factor of compliance readiness, with the manufacturers experiencing delayed approvals and difficulties in scheduling further appointments. In addition, the (EUROPEAN COMMISSION, 2025b) and (IQVIA, 2025) highlighted that systemic NB deficiencies are due to the backlog in conformity assessments currently to be performed under IVDR. With IVDR, in contrast to IVDD, where most IVDs could be self-

certified, there must be NB involvement on up to 90% of the devices, inevitably leading to a bottleneck (Cobbaert *et al.*, 2022). The impact of this scarcity as turning into actual-life risks in the context of this study is seen in qualitative responses, where firms reported cases of uncertainty on whether they would get NB slots within transitional timelines or whether they might not secure them at all, along with the risk of losing market access. These practice provides evidence linking the scarcity of NB to the possible reduction in the supply of kits (Baumgartner *et al.*, 2023); (Hallersten *et al.*, 2023).

Another obstacles were financial strains. Respondents cited rising expenses incurred in preparation of technical documentation, consultancy services, and expenditure on quality management system (QMS). Moreover, as per (MedTech Europe, 2025) and (Idink, 2025), who stated that financial capacities of large firms are not a major concern, but SMEs experience excessive financial costs, which can risk their survival. In addition, the survey findings represent non-uniform relationships between costs and readiness to comply, and the qualitative accounts are compatible with the suggestion that financial barriers to compliance are highly contingent. Further, when a firm has strong margins or a varied portfolio, cost management can be difficult, not decisive. Documentation requirements of IVDR also became a real keystone in regulation. Respondents reported the increased demand for clinical evidence, Performance Evaluation Report (PER), and Post-Market Surveillance (PMS) to be overwhelming, even when there were perceived to be conflicting or overlapping obligations. In addition, (Vasey *et al.*, 2022) and (Badnjević *et al.*, 2022) stated that the IVDR is considerably more burdensome in terms of administration as compared to IVDD. The length is further extended in the case of high-risk devices, as they require EU Reference Laboratory (EURL) testing as well (Valla *et al.*, 2021). These are also related to qualitative findings, where described frustrations with evidence expectations and frequent requests to clarify terminology.

Moreover, the technology impediments associated with the traceability and transparency requirements were present. There were issues raised that firms were finding it challenging to incorporate Unique Device Identification (UDI) systems and accommodate the European Database on Medical Devices (EUDAMED). Although set to enhance transparency, the needs come with huge investment and knowledge in IT. The issues outlined by (EUROPA, 2022) and (Thavayogarajah, 2021) suggest that most companies do not have the proper

infrastructure to accommodate the data-sensitive compliance requirements. According to (Khan, 2025) and (Khan and Goel, 2024), gaps in the fields of digital capacity and governance were especially acute in the cases of non-EU exporters. Moreover, NB bottlenecks and documentation backlogs were also seen to be a threat to innovation and market sustainability. Several respondents expressed overarching fears that they would miss out on having their products in the market, which may be a potential disruption in supply chains. In addition to this, (Laux *et al.*, 2024) state that the delays in IVDR approval with a decreased rate of innovation and amplified risks of diagnostic shortages. Therefore, the findings are informative in pointing out that the regulatory barriers and especially the scarcity of NBs, the high costs incurred, and the complexity of documentation are more systematic rather than temporary. The results validate prior literature and demonstrate the unevenness with which these barriers are experienced. The largest actors can absorb the costs and delays, whereas the smaller actors experience them as life-threatening. This study connects the available empirical evidence with the existing academic literature by highlighting that failure to systemically intervene in the current situation threatens IVDR to reduce the stakeholder base in the European diagnostic market, which would disprove the goal of making diagnostics safer and more reliable and fail to improve population health.

4.4.2 Analysis of Organisational Preparedness and Strategic Responses

At the current time, the regulatory barriers are a major challenge, but the study also indicated that organisations are not passive recipients of such constraints but would participate in various preparedness undertakings to deal with the transition to IVDR. When the data of quantitative and qualitative data were considered, it revealed that companies utilised tools like QMS restructuring, engagement of consultants, rationalisation of the portfolio, and digitalisation with relation to traceability. Quantitative analysis revealed that there was no significant relationship between the internal communication and organisational readiness to be able to predict compliance. Qualitative findings indicated that companies engaged in large-scale restructuring to ensure that their QMS complies with the IVDR needs. These restructurings involved controls on design, stronger management of suppliers, and stronger lifecycle documentation. In addition, as per (Sharma and Luthra, 2023) and (Kahles *et al.*, 2023), adaptive capacity is an important aspect of compliance. The deliberate incorporation of IVDR requirements in QMS frameworks showed that companies had a pragmatic and not

an official way towards readiness. However, these restructuring initiatives were also reported to be resource-demanding and disruptive by the participants. (Niclas Svensson, 2023) and (Gamarra and Karen, 2025) stated that these QMS upgrades enhance the robustness of compliance but may cause an excessive operational burden.

Furthermore, the contingency plan involved the wide application of third-party consultants and authorised agents. Most companies outsourced professional services to guide on technical documentation, development of PERs, and dealing with NBs. (Law *et al.*, 2023) and (Rajani *et al.*, 2022) emphasised that foreign exporters outside the EU usually rely to a great extent on consultants to overcome their knowledge deficit with respect to regulations. Although consultant dependency was considered to take its effect in the short run, various participants indicated that the factors of dependency and sustainability seem to be a matter of concern. In addition to this, Kearney et al. (2021) advised that the overuse of external actors can be detrimental to the formation of long-lived internal expertise. Another aspect that arose is portfolio rationalisation. A number of companies also indicated that they had cut the range of products, instead pursuing those that had stronger commercial or more certain regulatory prospects. This is in line with (Foster and Thelen, 2024) and (MB, 2022) that there were extensive product pull-offs as the companies shifted compliance resources to more profitable or even in-demand devices. Although this rationalisation can improve the efficiency of compliance, it threatens the diversity of the market and access to niche diagnostics (Hallersten *et al.*, 2023).

Moreover, digitalisation also formed a major readiness. Firms have invested in IT systems to support UDI, PMS, and EUDAMED reporting, and these can be quite expensive and technically complex. In addition, (Mondal, 2025), (Laux *et al.*, 2024), and (Thavayogarajah, 2021) stated that digital readiness is a condition to be able to comply with IVDR. Nevertheless, according to the participants of this study, especially non-EU exporters, digital systems were not aligned with the needs of the EU, which also supports the perspective of (Khan and Goel, 2024) regarding global digital infrastructure. One of the points of divergence between the literature and findings is on organisational communication. Although the survey findings indicated that a factor such as communication was not predictive of readiness, qualitative evidence indicated that shifting internal culture, like instilling the attitude of a compliance mindset across various departments, was deemed to be crucial. Furthermore, it

is identified that compliance culture is a critical factor and also indicates the less direct ways of influence on the part of communication by mediating through such strategic interventions as QMS organisation redesign or employee education. Therefore, the study establishes that organisational readiness is complex and requires structural, directional, and cultural adjustment. Literature only reinforces most of such strategies, but the research findings provide insight concerning the disruptive impacts of preparedness practices, the negative effects of over-dependence on outside expert assistance. In practice, the readiness of compliance is crafted through the combination of QMS reforms, the employment of consultants, the management of the portfolio, and digital capacity building.

4.4.3 Analysis of Perceived Benefits and Broader Implications

During the analysis, it was identified that the gains and implications not only of the IVDR but also regarding the path towards changes in the long run were observed despite the strong regulatory and organisational challenges. Statistical and descriptive data supported the fact of compliance with the achievements in patient safety, diagnostic reliability, market credibility, and organisational capability upgrading. Another aspect of the results was the attitudes about the ability to enhance diagnostic safety and reliability using IVDR. Survey evidence showed that there was a positive and significant relationship between compliance and an enhanced view of patient safety, with qualitative counterparts attesting that IVDR would serve the purpose of patient safety because devices would be based on much stronger evidence. These data validate the purpose of the IVDR, and EUR (2017) represents raising diagnostic sensitivity/specificity and the protection of the health of the population. In addition, (Cobbaert *et al.*, 2022), (Vasey *et al.*, 2022), and (Badnjević *et al.*, 2022) state the improvement of diagnostic validity by expanding requirements related to performance evaluation and PMS. This was further explained in participant narratives with firms noting that there is a significant cost to compliance, as a net effect, a better standard of products being released to the marketplace is being met.

The other major perceived benefit was market credibility and trust. Participants stated that the reputational gains accompanying timely compliance to enhance the relationship with NBs and regulators, as well as health providers. The transparency mechanisms were observed to promote accountability and the loss of secrets. In addition, (EUROPA, 2022) and (Laux *et al.*, 2024) stated the trust-promoting opportunities of the traceability systems. On the same

note, (MedTech Europe, 2025) observed that early adopters of IVDR placed themselves in a better competitive position to show strong compliance levels to their stakeholders. Another advantage is associated with capability development within an organisation. The participants shared their experiences of how IVDR caused companies to professionalise their QMS and instil more robust feedback loops, and enhance vigilance and PMS digital infrastructures. Moreover, (Hallersten *et al.*, 2023) and (Sharma and Luthra, 2023) state that regulation can serve as an organisational learning and resilience driver. In this view, IVDR should not be viewed as a compliance burden but, a driver of long-term capability upgrading. The results also showed that such benefits do not apply equally across companies: Larger firms were more inclined to use IVDR as the potential to strategically develop, whereas SMEs commonly perceived the requirements as impossible to address. Moreover (Mukherjee and Chanda, 2021) and (MedTech Europe (2025b) stated that SMEs can be locked out of competition in the European trade due to the new regime.

Respondents indicated that the IVDR would minimise the distribution of dubious diagnostics, which would increase the trust of society in healthcare systems in general. (Valla *et al.*, 2021) and (Ali *et al.*, 2022) stated that positioning IVDR as a systemic reform to boost diagnostic systems in Europe. Nonetheless, the respondents also indicated the possible unintended effects, such as the slowing innovation pace and the low availability of niche diagnostic products (Laux *et al.*, 2024) (Foster and Thelen, 2024). Moreover, it perceives IVDR as an upward adjustment of standards, and confidence construction is at risk of reducing market variety because the market mechanism is threatening to dislodge minor competitors. The implication of this is not only that the regulation succeeds because the oversight is sound, but that some supportive actions, like the simplification of NB procedures or SME oriented guidance, are required to make its benefits available throughout the industry. Therefore, the research represents the fact that IVDR compliance is accompanied by both short-term burdens and long-term benefits. Although costs are high, delays are considerable, and complexity is significant, organisations also realise that compliance provides better safety, credibility, and systemic trust. In addition, this work shows that IVDR has an impact on transformation; however, it is imperative to reduce inequalities in its implementation.

4.5 Summary

The results indicate that the majority of the respondents were mature professionals with different job positions in the Indian IVD manufacturing industry. The degree of organisational preparedness to become IVDR compliant was an average case, and there was high variance among different job functions and different IVD categories produced. The effectiveness of communication appeared as one of the main facilitators, and the certification delays, difficulties in getting access to the Notified Bodies, and long timeframes of CE marking became some of the obstacles on the way to readiness. Classes of products with an increased risk level had more considerable procedural and paperwork requirements. Nevertheless, most people believed that the IVDR improved the safety of more products and the reliability of the market, more so among Quality Assurance professionals and companies making products with higher risk. The discussion suggests that though IVDR compliance has tremendous regulatory and organisational interruptions. It also introduces a higher degree of safety, credibility, and resilience. The chapter also included a description of how the barriers, preparedness strategies, and perceived benefits matched the objectives of the study and supporting the dual burden-benefit aspects of the regulation.

Chapter 5

Conclusion and Recommendation

Chapter 5: Conclusion and Recommendation

5.1 Overall Conclusion

This study aimed to examine the regulatory challenges, organisational readiness, and perceived advantages of IVDR compliance for the IVDR. In addition, a mixed-methodology approach was considered in the above work, which combined quantitative analysis of data collected through a survey with qualitative thematic analysis. The study helped to critically examine the actions of organisations as they respond to the implementation of IVDR, the difficulties that they are facing, and the overall repercussions in terms of safety, trust, and competitiveness. Quantitative analysis indicated that the obstacles to IVDR compliance were Notified Body (NB) service access challenges, financial and economic costs, and documentation. These results are in line with the research question, since it was expected that regulatory issues would constitute the major setback. The targeted number of NBs has been a well-recognised issue and systemic capacity gaps after the implementation of MDR and IVDR. The recognised NBs are also limited in number, which causes a bottleneck that disadvantages smaller firms, who are unable to compete to get slots early to perform conformity assessments.

In addition, a financial burden has also been established as a core issue of concern. During the literature analysis, it was identified that the rates of expenses incurred were due to compliance. More expenses can include additional testing, staffing, and consultancy fees, which are structural problems for firms making the shift to the IVDR. This study provides a more complex interpretation as it demonstrates that cost is a major factor, but is not in all cases restrictive. The large firms had a better absorptive capacity as they considered the spending on compliance as an investment and not an existential threat. This indicates that regulatory costs are moderated by firm size and present financial constraints. Furthermore, the required evidence and documentation were another important obstacle identified during the analysis. The existing work highlighted the expanded clinical evidence standards of the IVDR, and especially high-risk tests, as a major obstacle. This study confirms that the high degree of paperwork not only consumes time and resources, but it also takes longer to access the market. Qualitative results also identified frustrations with unclear directions, which is consistent with the literature that raised concerns regarding the complexity of the regulation. Moreover, as per the analysis, it was determined that the firms capable of quality

management experience performed better in the documentation process, indicating that pre-existing regulatory maturity reduces some of the strain as a result.

The organisational preparedness was identified as a key factor in the success of compliance. Strategies that were used included QMS restructuring, utilisation of consultants, product portfolio rationalisation, and use of digital traceability systems, among others. Furthermore, during this study, communication was valuable as an indicator in a qualitative manner, but not statistically significant in the quantitative model. This difference sharpens the theoretical knowledge, as formality in communication is not sufficient to achieve readiness without systemic reorganisation. Qualitative and quantitative evidence showed that conformance with IVDR increased the safety of patients, diagnostic reliability, and credibility on the market, as well as organisational learning. The literature analysis showed that the IVDR is a tool to reinforce clinical evidence and mitigate risks with sufficient diagnostics. In addition, this study confirms that tougher demands led them to greater belief in the reliability of products. Improved trust was another positive because it shows that strong regulation enhances credibility among clinicians, patients, and the international markets.

However, this study also suggested the impact on the diversity of the market. Although regulation promotes systemic trust, SMEs stated that they were leaving less profitable niches to comply with what they considered excessive compliance costs. The larger firms benefit based on reputational and safety advantages, whereas the smaller firms are put at risk of their existence- a two-sided phenomenon that helps enhance the field of understanding on how IVDR has led to asymmetric impact. Therefore, the findings imply that IVDR compliance cannot be characterised only as a regulatory burden or enforcer of quality. Regulatory barriers and the supply of NBs and documentation requirements cannot be ignored; however, the organisation's preparedness strategies indicate how these barriers can be addressed. The comparison with literature presents a high degree of correspondence in the fundamental issues, as well as presents some crucial diverging points, mainly in the sector of cost distribution, as well as the role of communication and the unintended impacts in the SME sector. These findings show that firm characteristics and strategic selection mediate compliance outcomes.

5.2 Recommendations

Table 21: Major Recommendations

Category	Target Audience	Recommendation	Link to Findings
Practical	Policymakers & Regulators	Expand Notified Body (NB) capacity through faster accreditation and resource allocation.	The study confirmed that NB scarcity is the single most disruptive barrier to IVDR compliance, creating bottlenecks and uncertainty in market access. Increasing the number of accredited NBs and strengthening existing ones would reduce waiting times, ensure timely conformity assessments, and restore industry confidence.
Practical	Policymakers & Regulators	Provide clearer, harmonised, and practical guidance across EU member states.	Lack of clarity in documentation and clinical evidence requirements caused repeated delays and inefficiencies. Findings echoed the literature that criticised inconsistent interpretations between regulators. Standardised templates, technical guidance, and training workshops would minimise duplication, enhance predictability, and foster uniformity across the regulatory landscape.
Practical	Regulators & Industry Associations	Introduce targeted support mechanisms for SMEs	SMEs were disproportionately affected by high compliance costs and consultancy dependence. Without tailored support, SMEs risk market exit, reducing diagnostic diversity. Collaborative compliance models could lower costs and sustain smaller firms' competitiveness.
Practical	Organisations (Manufacturers & Suppliers)	Strengthen organisational preparedness through QMS restructuring, digitalisation, and product portfolio rationalisation.	Findings showed that communication alone was insufficient for preparedness. Firms that invested in systemic changes such as upgrading traceability systems, redesigning QMS, and focusing on high-value diagnostics were better positioned for compliance. This proactive strategy reduces long-term risk and builds resilience.
Academic	Researchers	Investigate SME versus large firm dynamics in IVDR compliance	The research revealed significant differences in how SMEs and larger firms absorb financial burdens and respond strategically. Further systematic studies could illuminate how resource asymmetries influence regulatory outcomes, ensuring more equitable policy frameworks.
Academic	Researchers	Examine digitalisation as an enabler of sustainable compliance	Firms adopting digital compliance and traceability tools showed greater efficiency and resilience. Academic research should explore the scalability, cost-effectiveness, and long-term sustainability of digital solutions across different firm sizes and contexts.
Academic	Researchers & Policy Analysts	Assess the long-term impact of IVDR on innovation and market diversity	While IVDR enhances patient safety and diagnostic credibility, this study found evidence of SMEs withdrawing from niche markets due to compliance burdens. Academic inquiry should evaluate the broader consequences for innovation ecosystems and patient access to specialised diagnostics.

5.3 Limitations and Contributions

This research has its weaknesses despite its great insight concerning the use of the IVDR. The sample size used was small in number, as the calculated sample size was 385, and the 171 valid responses were considered, hence limiting the generalisation of the findings to the wider IVD sector. Even though the findings provide insight into key tendencies, it would benefit external validity to use a bigger and more representative sample. The geographical scope of the research can also be viewed as a limitation since IVDR is a continent-wide regulation, and most of the evidence was collected based on the experience of the respondents representing particular geographic areas, thus possibly omitting the differences in preparedness and compliance rates in other member states. Besides, the use of self-reported survey and interview information poses a danger of response bias, whereby respondents might have either overstated their preparedness or underreported obstacles to present their organisations in a more positive light. The other limitation presented is that the research was cross-sectional. Because compliance is a process that is changing over time, the analysis presented here may never be complete, as organisations are still adjusting their approach to IVDR implementation. Moreover, thematic analysis of qualitative findings provided a richer understanding; however, by necessity, the analysis was population-specific, and mapping the data using a different coding scheme might shed a different light on the organisational culture or experience of regulation.

Notwithstanding these limitations, the research has a number of important contributions to make. Empirically, this helps in increasing knowledge through combining both the quantitative and qualitative aspects to investigate regulatory barriers, organisational preparedness, and perceived benefit to the new IVDR compliance. There is also a more solid image to this approach than there was with research looking into each of these factors separately. At a more theoretical level, the findings take a step towards building out existing studies of regulatory compliance by demonstrating how firm size, access to resources, and strategising towards adaptation contribute to compliance and go beyond a single-minded disclosure that IVDR is nothing more than difficult. The study is also practical, giving evidence-based suggestions to policymakers and organisations. To regulators, the report highlights the sense of urgency around the shortage of Notified Bodies, the need to harmonise more aid and guidance, and to target assistance to SMEs. In addition, the results emphasise

structural preparedness investments like QMS restructuring and digitalisation as the key to long-term compliance resilience. Methodologically, the dissertation is relevant to understanding regulatory change and shows the mixed methods approach, allowing a more in-depth and detailed interpretation of more complex industry transitions.

5.4 Suggestions for Future Research

The study has validated important considerations about IVDR compliance issues and approaches; however, it leaves room to explore more. An important trend in future research opportunities arises by way of conducting longitudinal research to follow organisations over time and to capture the evolution of compliance strategies as the regulated environment matures over time. Since the work at hand relied on a cross-sectional approach, in the future, it should consider the observed adaptations, including portfolio rationalisation, digitalisation, and QMS restructuring, to trigger competitive advantages long term or unexpected effects in the marketplace. The other area that holds a great, promising activity is in comparative research. As IVDR is a global tendency to tighten the regulation of medical technologies, further research can be offered to compare its implementation to other models, such as the Medical Device Regulation (MDR) in the EU or any equivalent solution. Comparative analysis would not only bring the best practices but would also demonstrate the existence of disproportionate burdens as compared to other similar regulatory systems. Also, the research should focus on the variant effects of IVDR on smaller companies and larger organisations. Resource asymmetry was emphasised in this dissertation as one of the critical matters influencing preparedness; however, future research should more closely investigate how the structural disadvantages that SMEs can endure need to be mitigated. Specifically, they could investigate how fee cuts, shared compliance capacity, or digital traceability systems could be similar to the smaller firms. Moreover, the unintended consequences of IVDR on innovation and market diversity can be discussed. Although the regulation has improved the safety and reliability of diagnosis, it implies a threat of product withdrawal and decreased product. It would be important to address how these changes are influencing innovation ecosystems and patient access to specialised diagnostics over time. Through the provided answers to questions, future studies will be able to develop research that will contribute to a more in-depth and penetrating analysis of regulatory transitions within the diagnostics field.

5.5 Final Reflection

Writing this dissertation is a thoroughly challenging yet gratifying experience. The undertaking of examining the complexities of a policy as the IVDR, has made me a more discerning thinker about regulatory frameworks and any communalisation of the problems being sponsored by such frameworks, as well as an individual who better understands the difficulty facing organisations to adapt to changes in policy, where the changes cannot be underestimated. By integrating both quantitative and more qualitative methods, I learned to contrast statistically based evidence with lived organisational experiences, which are very important to research. In addition to technical competencies, the work has enhanced my critical thinking, project management skills, and academic writing skills, which in the long run, will not be a dispensable capability. More importantly, the paper has highlighted the fact that no regulation can work in isolation as its efficacy is determined by the congruence of the policy spirit, organisational capability, and stakeholder involvement. Moreover, the reflective process has confirmed to me on notion of evidence-based inquiry as a source of effective and practical contributions.

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APPENDICES

Appendix A: SPSS Output Frequencies

Statistics-

Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?	Do you have at least two years of professional experience in Regulatory Affairs, Quality Assurance or Compliance inside the IVD sector?	In which area do you work currently?	How many years of professional experience do you have in the IVD industry?	Which class of IVD kits does your organisation manufacture?	Which classes of medical devices does it export to the EU?	How equipped is your organisation for IVDR 2017/746 compliance?	Has your organisation conducted any of the following actions in response to IVDR?	Have you reorganised your Quality Management System (QMS) to meet IVDR requirements?	What new reports or studies were required due to the new IVDR?	Which area posed the highest challenge during the transition from IVDD to IVDR?	Has your organisation required outside consultancy to support IVDR compliance?	Which key documents have been updated to comply with IVDR?	Rate the level of difficulty in accessing a Notified Body for IVDR certification.	How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	To what extent has IVDR impacted regulatory costs for your organisation?	Have you experienced delay in obtaining CE marking under the new IVDR?	What is the estimated average time taken to get CE marking under IVDR?	Compared to your organisation's past experience with CE marking under the IVDD, how would you describe this timeframe?	Do you agree that the EU IVDR 2017/746 increases product safety and market reliability?

											transition from IVDD to IVDR?											
N	Valid	181	175	171	171	171	171	171	171	171	171	171	171	171	171	171	171	171	171	171	171
	Missing	1	7	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11	11
Mean		1.03	1.02	2.26	1.78	2.69	2.68	2.27	2.01	2.53	2.13	2.57	1.50	2.37	2.52	2.80	3.14	1.71	2.32	2.66	1.98
Std. Error of Mean		.013	.011	.073	.059	.074	.072	.070	.074	.090	.083	.081	.046	.072	.088	.092	.086	.051	.065	.072	.066
Median		1.00	1.00	2.00	2.00	3.00	3.00	2.00	2.00	2.00	2.00	3.00	1.00	2.00	2.00	3.00	3.00	2.00	2.00	3.00	2.00
Mode		1	1	2	1	3	3	3	1	4	1	3	1	3	2	3	3	2	2	3	2

Std. Deviation	.180	.150	.960	.771	.972	.936	.921	.970	1.175	1.084	1.057	.598	.939	1.144	1.206	1.124	.666	.845	.940	.864
Variance	.032	.022	.922	.594	.945	.876	.848	.941	1.380	1.176	1.117	.357	.883	1.310	1.454	1.263	.443	.714	.884	.747
Skewness	5.259	6.441	.230	.394	-.237	-.113	.066	.602	.032	.401	-.255	.764	.004	.283	.084	-.180	.411	.279	-.389	.587
Std. Error of Skewness	.181	.184	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186	.186
Kurtosis	25.945	39.940	-.917	-1.215	-.912	-.898	-.940	-.662	-1.491	-1.190	-1.151	-.381	-.928	-.929	-.948	-.666	-.762	-.451	-.699	-.308
Std. Error of Kurtosis	.359	.365	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369	.369
Range	1	1	3	2	3	3	3	3	3	3	3	2	3	4	4	4	2	3	3	3
Minimum	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Maximum	2	2	4	3	4	4	4	4	4	4	4	3	4	5	5	5	3	4	4	4
Sum	187	179	386	305	460	459	389	344	433	365	440	256	406	431	479	537	292	397	455	339
Percentiles 25	1.00	1.00	1.00	1.00	2.00	2.00	2.00	1.00	1.00	1.00	2.00	1.00	2.00	2.00	2.00	2.00	1.00	2.00	2.00	1.00

50	1.00	1.00	2.00	2.00	3.00	3.00	2.00	2.00	2.00	2.000	3.00	1.00	2.00	2.00	3.00	3.00	2.00	2.00	3.00	2.000
75	1.00	1.00	3.00	2.00	3.00	3.00	3.00	3.00	4.00	3.000	3.00	2.00	3.00	3.00	4.00	4.00	2.00	3.00	3.00	2.000

Frequency Table

Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	175	96.2	96.7	96.7
	No	6	3.3	3.3	100.0
	Total	181	99.5	100.0	
Missing	System	1	.5		
Total		182	100.0		

Do you have at least two years of professional experience in Regulatory Affairs, Quality Assurance or Compliance inside the IVD sector?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	171	94.0	97.7	97.7
	No	4	2.2	2.3	100.0
	Total	175	96.2	100.0	
Missing	System	7	3.8		
Total		182	100.0		

In which area do you work currently?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Regulatory Affairs	43	23.6	25.1	25.1
	Quality Assurance	60	33.0	35.1	60.2
	Compliance management	49	26.9	28.7	88.9
	Product Management	19	10.4	11.1	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

How many years of professional experience do you have in the IVD industry?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2–5 years	73	40.1	42.7	42.7
	6–10 years	62	34.1	36.3	78.9
	More than 10 years	36	19.8	21.1	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Which class of IVD kits does your organisation manufacture?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Class A	23	12.6	13.5	13.5
	Class B	46	25.3	26.9	40.4
	Class C	63	34.6	36.8	77.2
	Class D	39	21.4	22.8	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Which class of medical devices does it export to the EU?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Class A	18	9.9	10.5	10.5
	Class B	56	30.8	32.7	43.3
	Class C	59	32.4	34.5	77.8
	Class D	38	20.9	22.2	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

How equipped is your organisation for IVDR 2017/746 compliance?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Fully compliant	41	22.5	24.0	24.0
	Partially compliant	56	30.8	32.7	56.7
	Not compliant	60	33.0	35.1	91.8
	In progress	14	7.7	8.2	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Has your organisation conducted any of the following actions in response to IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Upskilled existing employees through IVDR-related training	63	34.6	36.8	36.8
	Hired new employees in regulatory/quality departments	59	32.4	34.5	71.3
	Restructured internal teams or departments	33	18.1	19.3	90.6
	Increased budget allocation to compliance	16	8.8	9.4	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Have you reorganised your Quality Management System (QMS) to meet IVDR requirements?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	43	23.6	25.1	25.1
	No	47	25.8	27.5	52.6
	Not sure	28	15.4	16.4	69.0
	In progress	53	29.1	31.0	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

What new reports or studies were required during the transition from IVDD to IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Performance Evaluation Reports (PER)	66	36.3	38.6	38.6
	Post-Market Performance Follow-Up (PMPF)	40	22.0	23.4	62.0
	Clinical Performance Studies	41	22.5	24.0	86.0
	Risk Management File	24	13.2	14.0	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Which area posed the highest challenge during the transition from IVDD to IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Clinical evaluation	39	21.4	22.8	22.8
	Documentation complexity	30	16.5	17.5	40.4
	Notified Body delays	67	36.8	39.2	79.5
	Internal resource limitations	35	19.2	20.5	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Has your organisation required outside consultancy to support IVDR compliance?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	95	52.2	55.6	55.6
	No	67	36.8	39.2	94.7
	Not sure	9	4.9	5.3	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Which key documents have been updated to comply with IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Technical Documentation	36	19.8	21.1	21.1
	Performance Evaluation Report (PER)	54	29.7	31.6	52.6
	Post-Market Performance Follow-up (PMPF)	62	34.1	36.3	88.9
	Clinical Evidence Documentation	19	10.4	11.1	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Rate the level of difficulty in accessing a Notified Body for IVDR certification.

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very easy	37	20.3	21.6	21.6
	Somewhat easy	55	30.2	32.2	53.8
	Difficult	38	20.9	22.2	76.0
	Very difficult	35	19.2	20.5	96.5
	Not attempted	6	3.3	3.5	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very effective	29	15.9	17.0	17.0
	Moderately effective	43	23.6	25.1	42.1
	Poor	46	25.3	26.9	69.0
	Not applicable	39	21.4	22.8	91.8

	5	14	7.7	8.2	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

To what extent has IVDR impacted regulatory costs for your organisation?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Major increase	15	8.2	8.8	8.8
	Minor increase	33	18.1	19.3	28.1
	No impact	55	30.2	32.2	60.2
	Minor decrease	49	26.9	28.7	88.9
	Major decrease.	19	10.4	11.1	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Have you experienced delay in obtaining CE marking under the new IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	70	38.5	40.9	40.9
	No	81	44.5	47.4	88.3
	Not applicable	20	11.0	11.7	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

What is the estimated average time taken to get CE marking under IVDR?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Less than 6 months	26	14.3	15.2	15.2
	6–12 months	80	44.0	46.8	62.0
	Over 12 months	49	26.9	28.7	90.6

	No CE marking obtained yet	16	8.8	9.4	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Compared to your organisation's past experience with CE marking under the IVDD, how would you describe this timeframe?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Faster than IVDD	26	14.3	15.2	15.2
	About the same as IVDD	36	19.8	21.1	36.3
	Slower than IVDD	79	43.4	46.2	82.5
	Not sure / No prior IVDD experience	30	16.5	17.5	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Do you agree that the EU IVDR 2017/746 increases product safety and market reliability?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Strongly agree	55	30.2	32.2	32.2
	Agree	74	40.7	43.3	75.4
	Disagree	32	17.6	18.7	94.2
	Strongly disagree	10	5.5	5.8	100.0
	Total	171	94.0	100.0	
Missing	System	11	6.0		
Total		182	100.0		

Oneway ANOVA

How equipped is your organisation for IVDR 2017/746 compliance?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.441	3	.147	.171	.916
Within Groups	143.641	167	.860		
Total	144.082	170			

Post Hoc Tests

Multiple Comparisons

Dependent Variable: How equipped is your organisation for IVDR 2017/746 compliance?

Tukey HSD

(I) Which class of IVD kits does your organisation manufacture?	(J) Which class of IVD kits does your organisation manufacture?	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Class A	Class B	-.087	.237	.983	-.70	.53
	Class C	-.009	.226	1.000	-.60	.58
	Class D	.056	.244	.996	-.58	.69
Class B	Class A	.087	.237	.983	-.53	.70
	Class C	.078	.180	.973	-.39	.54
	Class D	.143	.202	.894	-.38	.67
Class C	Class A	.009	.226	1.000	-.58	.60
	Class B	-.078	.180	.973	-.54	.39
	Class D	.065	.189	.986	-.43	.56
Class D	Class A	-.056	.244	.996	-.69	.58
	Class B	-.143	.202	.894	-.67	.38
	Class C	-.065	.189	.986	-.56	.43

Homogeneous Subsets

How equipped is your organisation for IVDR 2017/746 compliance?

Tukey HSD[a,b]

Which class of IVD kits does your organisation manufacture?	N	Subset for alpha = 0.05 1
Class D	39	2.21
Class A	23	2.26
Class C	63	2.27
Class B	46	2.35
Sig.		.910

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 37.477.

b. The group sizes are unequal. The harmonic mean of the group sizes is used. Type I error levels are not guaranteed.

Means Plots

Oneway

ANOVA

Rate the level of difficulty in accessing a Notified Body for IVDR certification.

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	13.836	3	4.612	3.688	.013
Within Groups	208.842	167	1.251		
Total	222.678	170			

Post Hoc Tests

Multiple Comparisons

Dependent Variable: Rate the level of difficulty in accessing a Notified Body for IVDR certification.

Tukey HSD

(I) Which class of medical devices does it export to the EU?	(J) Which class of medical devices does it export to the EU?	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Class A	Class B	.472	.303	.405	-.31	1.26
	Class C	-.142	.301	.965	-.92	.64
	Class D	.433	.320	.531	-.40	1.26
Class B	Class A	-.472	.303	.405	-1.26	.31
	Class C	-.614*	.209	.019	-1.16	-.07
	Class D	-.039	.235	.998	-.65	.57
Class C	Class A	.142	.301	.965	-.64	.92
	Class B	.614*	.209	.019	.07	1.16
	Class D	.575	.233	.068	-.03	1.18
Class D	Class A	-.433	.320	.531	-1.26	.40
	Class B	.039	.235	.998	-.57	.65
	Class C	-.575	.233	.068	-1.18	.03

*. The mean difference is significant at the 0.05 level.

Homogeneous Subsets

Rate the level of difficulty in accessing a Notified Body for IVDR certification.

Tukey HSD[a,b]

Which class of medical devices does it export to the EU?	N	Subset for alpha = 0.05 1
Class B	56	2.25
Class D	38	2.29
Class A	18	2.72
Class C	59	2.86
Sig.		.108

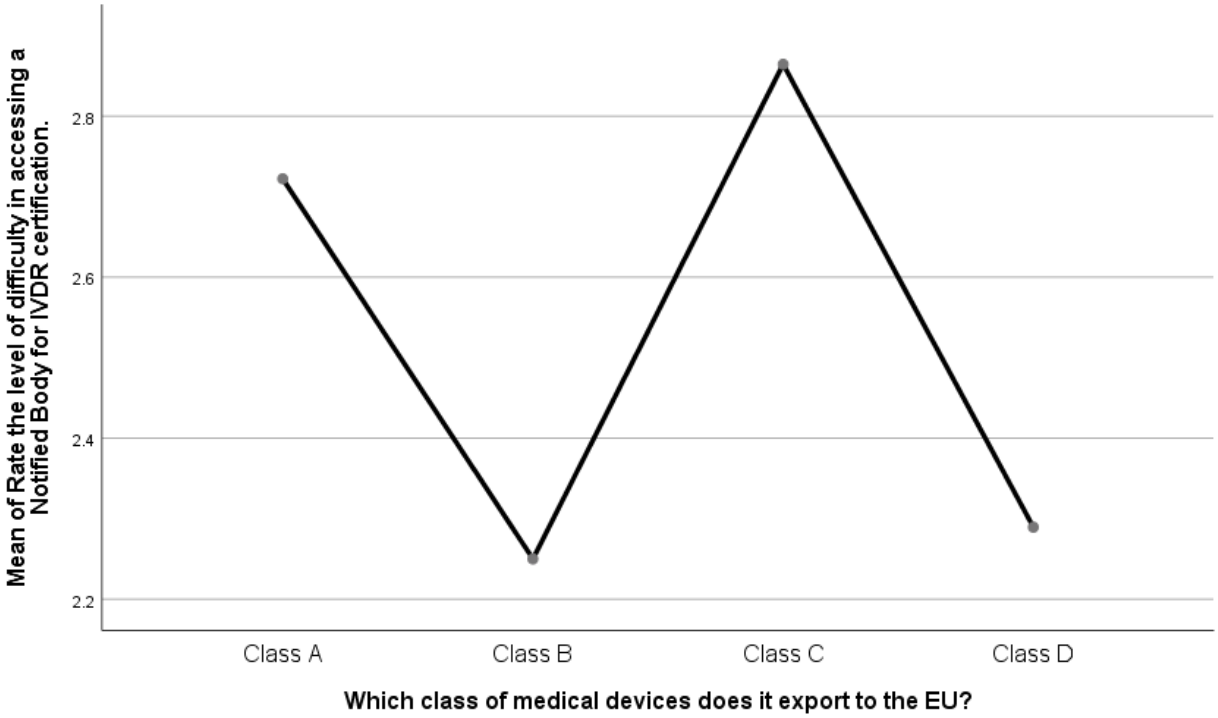
Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 34.282.

b. The group sizes are unequal. The harmonic mean of the group sizes is used.

Type I error levels are not guaranteed.

Means Plots



Oneway

ANOVA

How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition

	Sum of Squares	df	Mean Square	F	Sig.

Between Groups	23.060	3	7.687	5.726	.001
Within Groups	224.180	167	1.342		
Total	247.240	170			

Post Hoc Tests

Multiple Comparisons

Dependent Variable: How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition

Tukey HSD

(I) In which area do you work currently?	(J) In which area do you work currently?	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
Regulatory Affairs	Quality Assurance	.833*	.231	.002	.23	1.43
	Compliance management	.518	.242	.145	-.11	1.15
	Product Management	-.083	.319	.994	-.91	.75
Quality Assurance	Regulatory Affairs	-.833*	.231	.002	-1.43	-.23
	Compliance management	-.314	.223	.496	-.89	.26
	Product Management	-.916*	.305	.016	-1.71	-.12
Compliance management	Regulatory Affairs	-.518	.242	.145	-1.15	.11
	Quality Assurance	.314	.223	.496	-.26	.89
	Product Management	-.602	.313	.223	-1.41	.21
Product Management	Regulatory Affairs	.083	.319	.994	-.75	.91
	Quality Assurance	.916*	.305	.016	.12	1.71
	Compliance management	.602	.313	.223	-.21	1.41

*. The mean difference is significant at the 0.05 level.

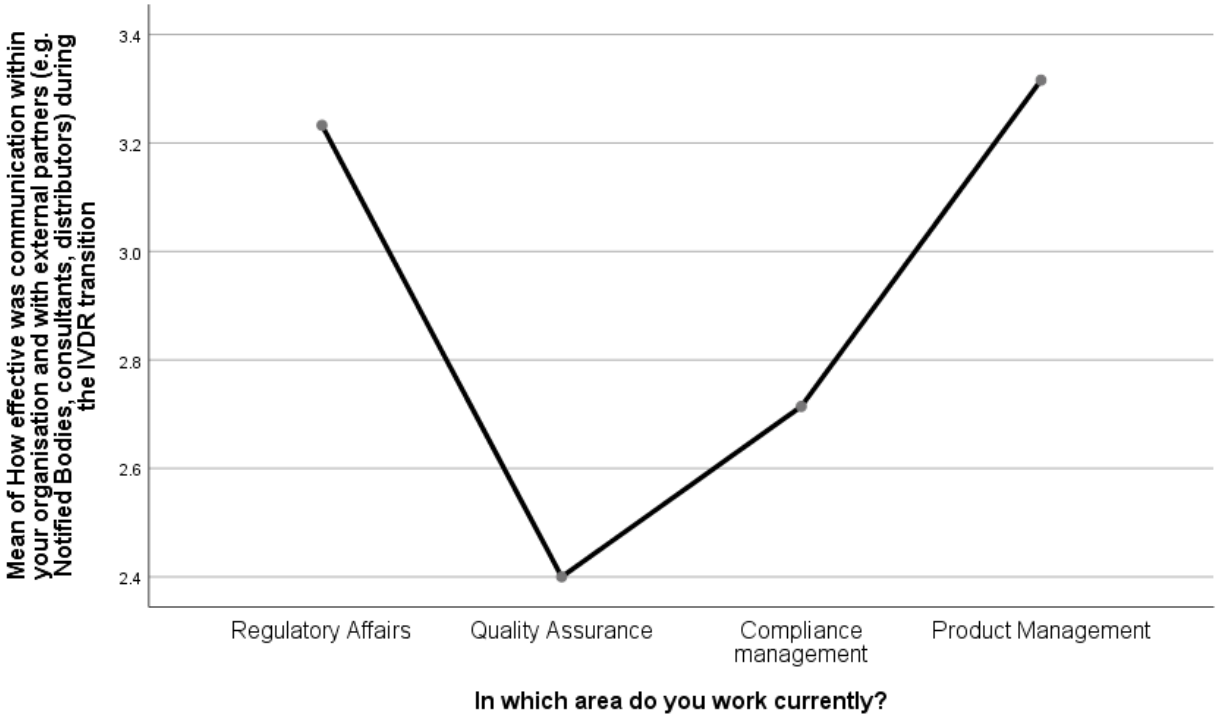
Homogeneous Subsets

How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition

Tukey HSD[a,b]

In which area do you work currently?	N	Subset for alpha = 0.05	
		1	2
Quality Assurance	60	2.40	
Compliance management	49	2.71	2.71
Regulatory Affairs	43		3.23
Product Management	19		3.32
Sig.		.664	.132

Means Plots



Correlations

a

		How equipped is your organisation for IVDR 2017/746 compliance?	Rate the level of difficulty in accessing a Notified Body for IVDR certification.	How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	To what extent has IVDR impacted regulatory costs for your organisation?	What is the estimated average time taken to get CE marking under IVDR?
How equipped is your organisation for IVDR 2017/746 compliance?	Pearson Correlation	1	-.148	-.056	.036	.075
	Sig. (2-tailed)		.054	.463	.636	.331
	N	171	171	171	171	171
Rate the level of difficulty in accessing a Notified Body for IVDR certification.	Pearson Correlation	-.148	1	.335**	.213**	.063
	Sig. (2-tailed)	.054		.000	.005	.412
	N	171	171	171	171	171
How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	Pearson Correlation	-.056	.335**	1	.021	-.151*
	Sig. (2-tailed)	.463	.000		.788	.049
	N	171	171	171	171	171
To what extent has IVDR impacted regulatory costs for your organisation?	Pearson Correlation	.036	.213**	.021	1	-.054
	Sig. (2-tailed)	.636	.005	.788		.483
	N	171	171	171	171	171

What is the estimated average time taken to get CE marking under IVDR?	Pearson Correlation	.075	.063	-.151*	-.054	1
	Sig. (2-tailed)	.331	.412	.049	.483	
	N	171	171	171	171	171

Regression

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.187[a]	.035	.012	.915	.035	1.496	4	166	.206

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.013	4	1.253	1.496	.206[b]
	Residual	139.069	166	.838		
	Total	144.082	170			

Coefficients[a]

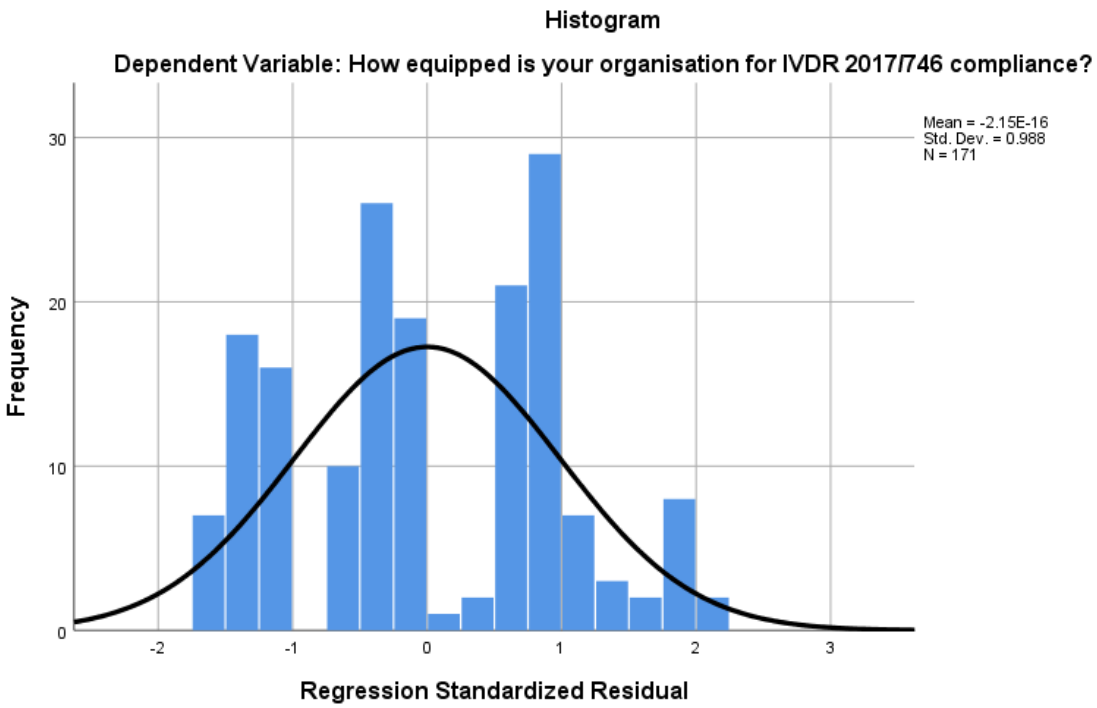
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	2.164	.351		6.173	.000
	Rate the level of difficulty in accessing a Notified Body for IVDR certification.	-.141	.067	-.175	-2.091	.038
	How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	.011	.063	.015	.176	.860
	To what extent has IVDR impacted regulatory costs for your organisation?	.064	.064	.078	.999	.319

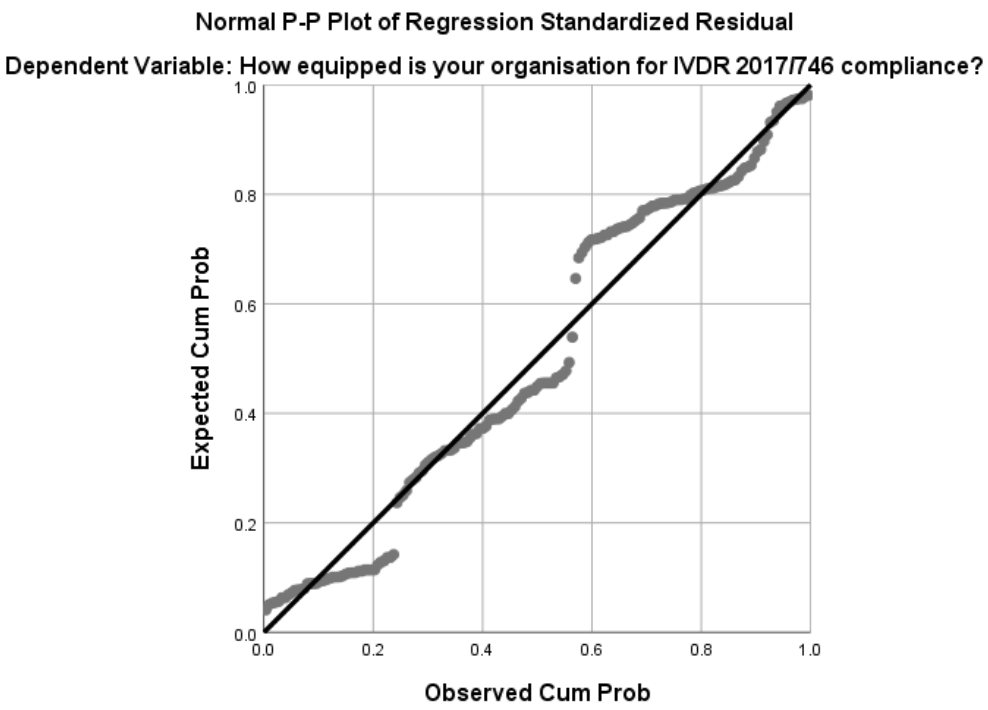
What is the estimated average time taken to get CE marking under IVDR?	.101	.085	.092	1.183	.239

Residuals Statistics[a]

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.84	2.78	2.27	.172	171
Residual	-1.592	1.896	.000	.904	171
Std. Predicted Value	-2.506	2.937	.000	1.000	171
Std. Residual	-1.740	2.071	.000	.988	171

Charts





T-Test

Group Statistics

	Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?	N	Mean	Std. Deviation	Std. Error Mean
How equipped is your organisation for IVDR 2017/746 compliance?	Yes	171	2.27	.921	.070
	No	0[a]	.	.	.

a. t cannot be computed because at least one of the groups is empty.

T-Test

Group Statistics

	Has your organisation required outside consultancy to support IVDR compliance?	N	Mean	Std. Deviation	Std. Error Mean
Rate the level of difficulty in accessing a Notified Body for IVDR certification.	Yes	95	2.47	1.128	.116
	No	67	2.66	1.188	.145

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Rate the level of difficulty in accessing a Notified Body for IVDR certification.	Equal variances assumed	.505	.478	-.995	160	.321	-.183	.184	-.546	.180
	Equal variances not assumed			-.986	137.616	.326	-.183	.186	-.550	.184

T-Test

Group Statistics

	Have you experienced delay in obtaining CE marking under the new IVDR?	N	Mean	Std. Deviation	Std. Error Mean
	Yes	70	2.79	1.215	.145

How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	No	81	2.80	1.177	.131

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition	Equal variances assumed	.464	.497	-.086	149	.932	-.017	.195	-.402	.368
	Equal variances not assumed			-.086	144.411	.932	-.017	.195	-.403	.369

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * In which area do you work currently?	171	94.0%	11	6.0%	182	100.0%
Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * Which class of medical devices does it export to the EU?	171	94.0%	11	6.0%	182	100.0%
Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * Which class of IVD kits does your organisation manufacture?	171	94.0%	11	6.0%	182	100.0%
Has your organisation required outside consultancy to support IVDR compliance? * In which area do you work currently?	171	94.0%	11	6.0%	182	100.0%
Has your organisation required outside consultancy to support IVDR compliance? * Which class of medical devices does it export to the EU?	171	94.0%	11	6.0%	182	100.0%
Has your organisation required outside consultancy to support IVDR compliance? * Which class of IVD kits does your organisation manufacture?	171	94.0%	11	6.0%	182	100.0%
Have you experienced dealy in obtaining CE marking under the new IVDR? * In which area do you work currently?	171	94.0%	11	6.0%	182	100.0%

Have you experienced delay in obtaining CE marking under the new IVDR? * Which class of medical devices does it export to the EU?	171	94.0%	11	6.0%	182	100.0%
Have you experienced delay in obtaining CE marking under the new IVDR? * Which class of IVD kits does your organisation manufacture?	171	94.0%	11	6.0%	182	100.0%

Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * In which area do you work currently?

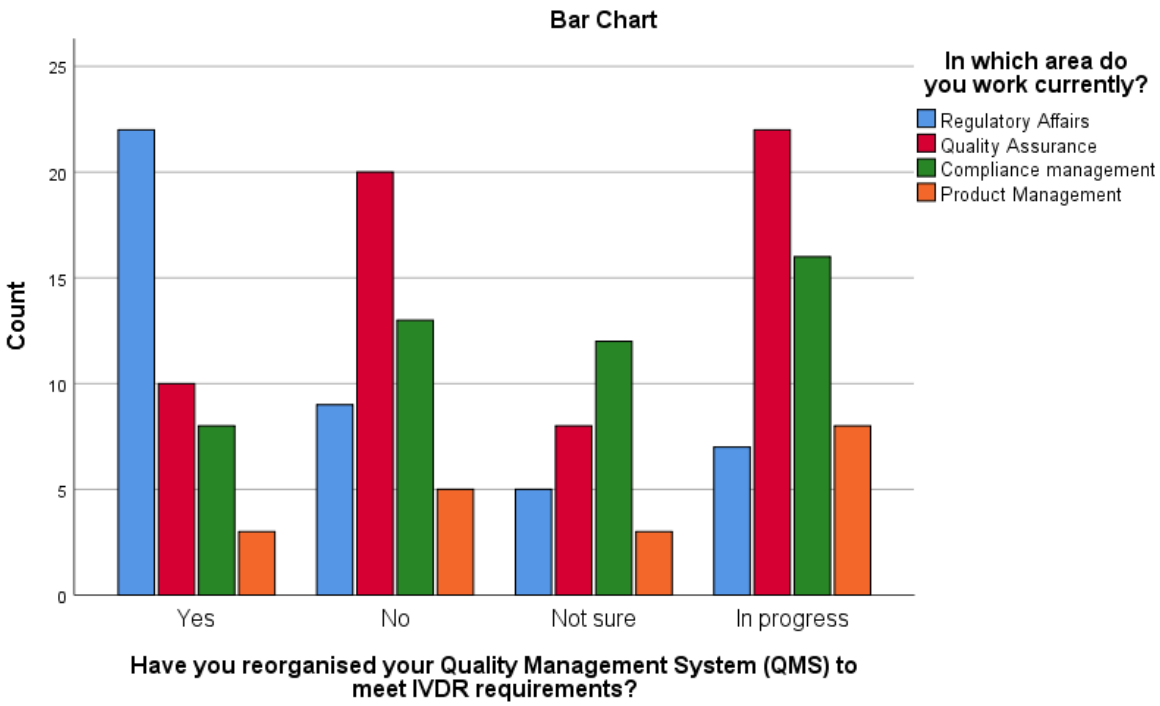
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	24.244[a]	9	.004
Likelihood Ratio	22.466	9	.008
Linear-by-Linear Association	10.474	1	.001
N of Valid Cases	171		

a. 2 cells (12.5%) have expected count less than 5. The minimum expected count is 3.11.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.377	.004
	Cramer's V	.217	.004
N of Valid Cases		171	



Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * Which class of medical devices does it export to the EU?

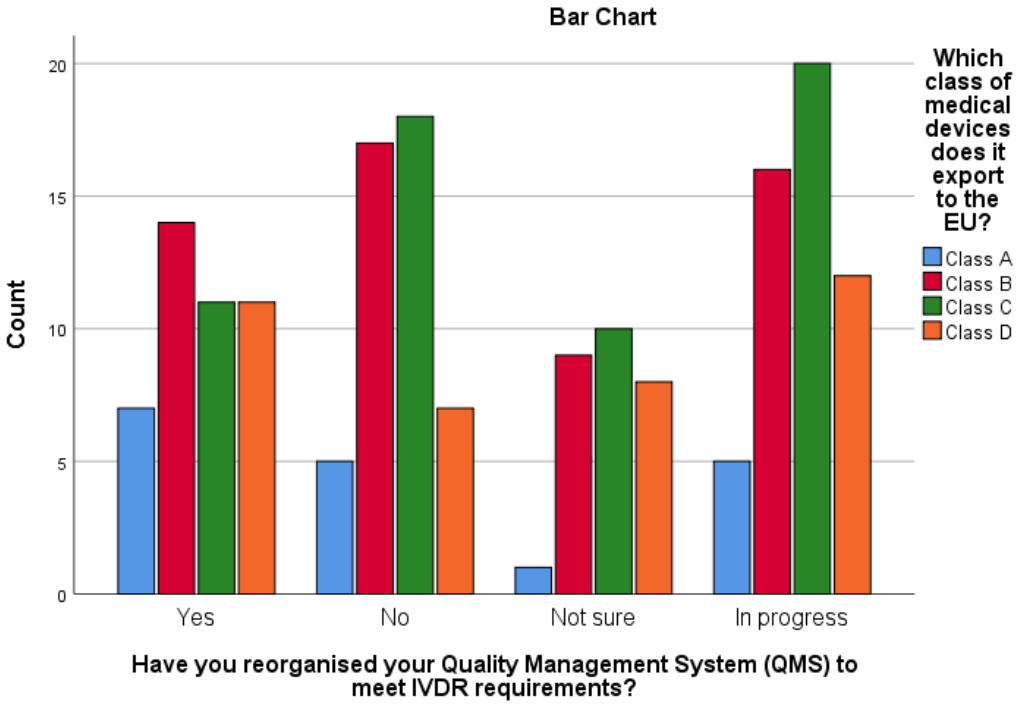
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	6.204[a]	9	.719
Likelihood Ratio	6.639	9	.675
Linear-by-Linear Association	1.057	1	.304
N of Valid Cases	171		

a. 3 cells (18.8%) have expected count less than 5. The minimum expected count is 2.95.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.190	.719
	Cramer's V	.110	.719
N of Valid Cases		171	



Have you reorganised your Quality Management System (QMS) to meet IVDR requirements? * Which class of IVD kits does your organisation manufacture?

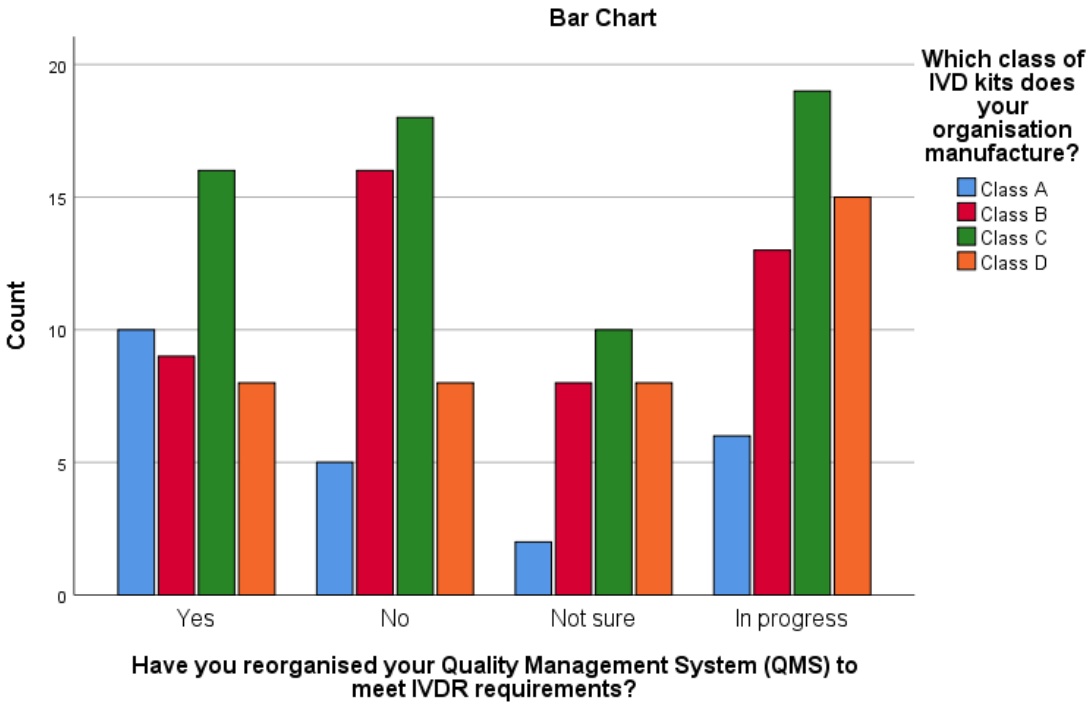
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	8.143[a]	9	.520
Likelihood Ratio	7.781	9	.556
Linear-by-Linear Association	2.867	1	.090
N of Valid Cases	171		

a. 1 cells (6.3%) have expected count less than 5. The minimum expected count is 3.77.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.218	.520
	Cramer's V	.126	.520
N of Valid Cases		171	



Has your organisation required outside consultancy to support IVDR compliance? * In which area do you work currently?

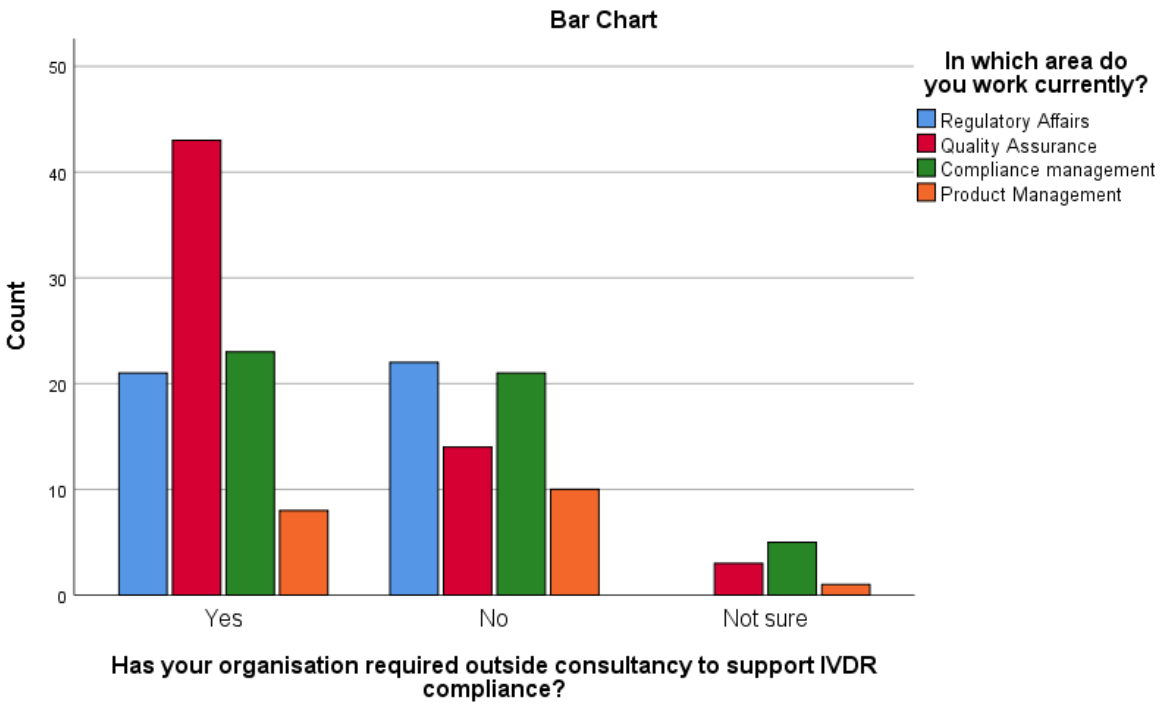
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	15.438[a]	6	.017
Likelihood Ratio	17.506	6	.008
Linear-by-Linear Association	2.212	1	.137
N of Valid Cases	171		

a. 4 cells (33.3%) have expected count less than 5. The minimum expected count is 1.00.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.300	.017
	Cramer's V	.212	.017
N of Valid Cases		171	



Has your organisation required outside consultancy to support IVDR compliance? * Which class of medical devices does it export to the EU?

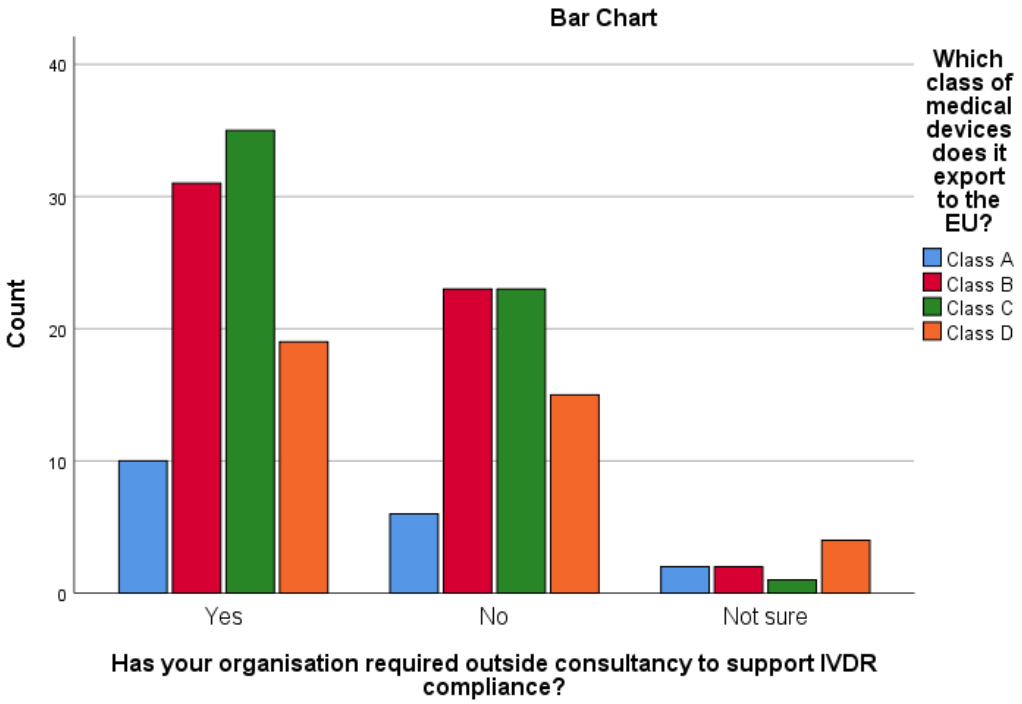
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5.473[a]	6	.485
Likelihood Ratio	5.300	6	.506
Linear-by-Linear Association	.152	1	.697
N of Valid Cases	171		

a. 4 cells (33.3%) have expected count less than 5. The minimum expected count is .95.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.179	.485
	Cramer's V	.127	.485
N of Valid Cases		171	



Has your organisation required outside consultancy to support IVDR compliance? * Which class of IVD kits does your organisation manufacture?

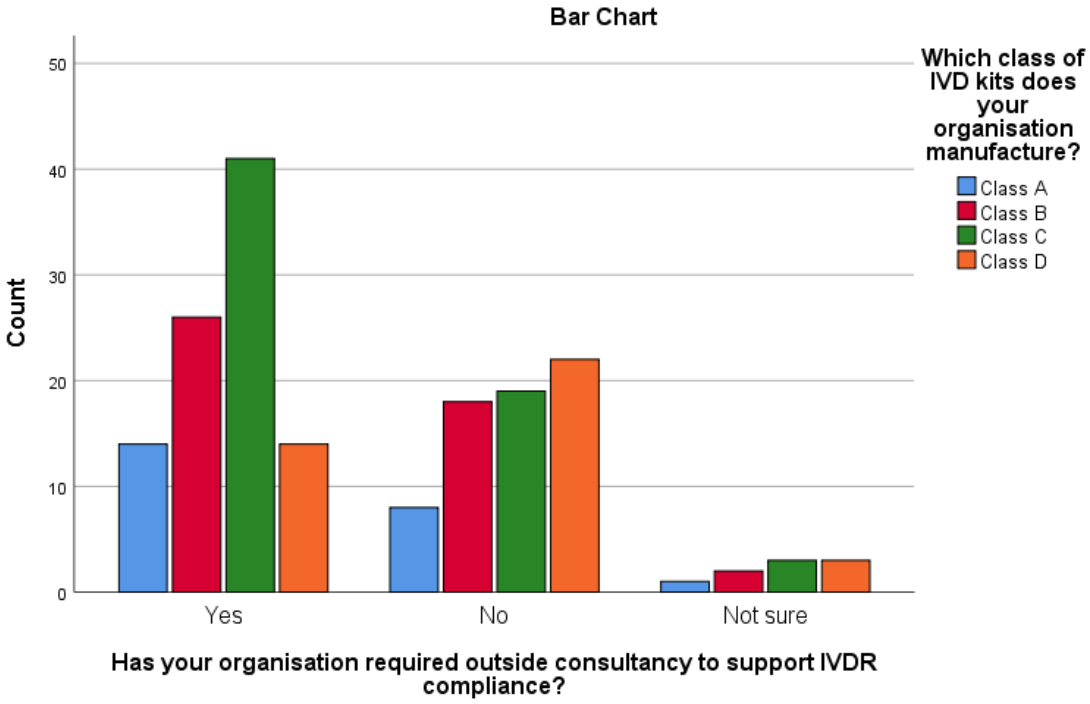
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	8.820[a]	6	.184
Likelihood Ratio	8.869	6	.181
Linear-by-Linear Association	2.656	1	.103
N of Valid Cases	171		

a. 4 cells (33.3%) have expected count less than 5. The minimum expected count is 1.21.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.227	.184
	Cramer's V	.161	.184
N of Valid Cases		171	



Have you experienced delay in obtaining CE marking under the new IVDR? * In which area do you work currently?

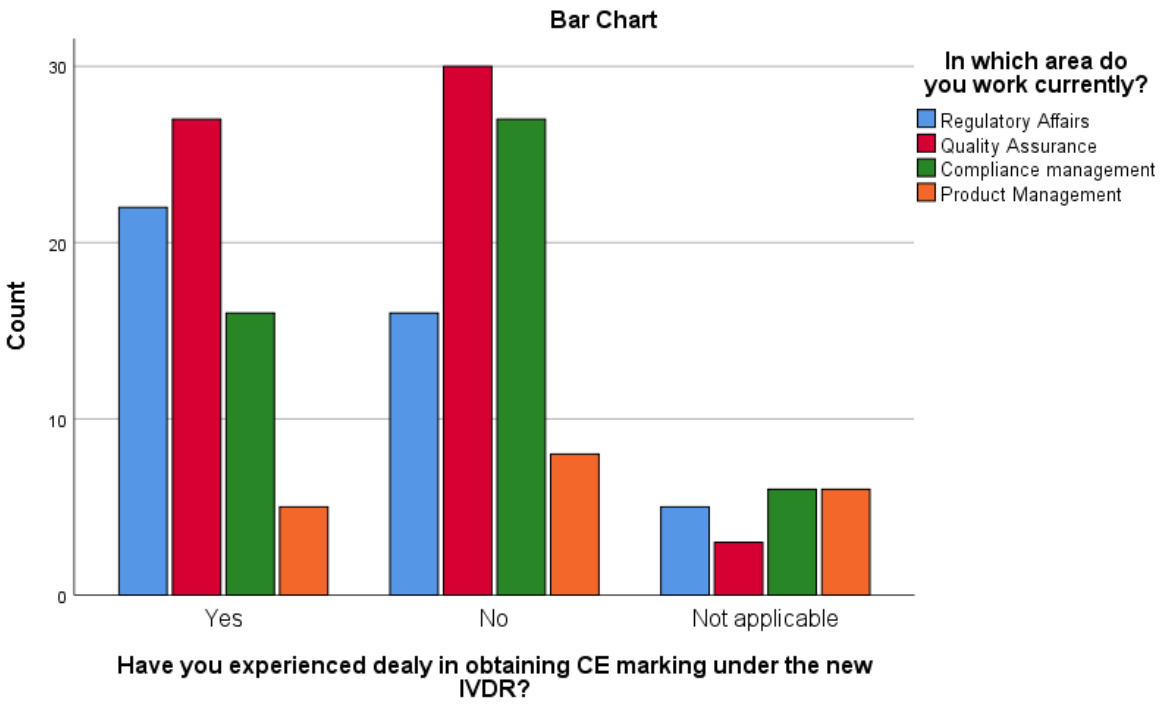
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	13.644[a]	6	.034
Likelihood Ratio	12.385	6	.054
Linear-by-Linear Association	6.882	1	.009
N of Valid Cases	171		

a. 1 cells (8.3%) have expected count less than 5. The minimum expected count is 2.22.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.282	.034
	Cramer's V	.200	.034
N of Valid Cases		171	



Have you experienced delay in obtaining CE marking under the new IVDR? * Which class of medical devices does it export to the EU?

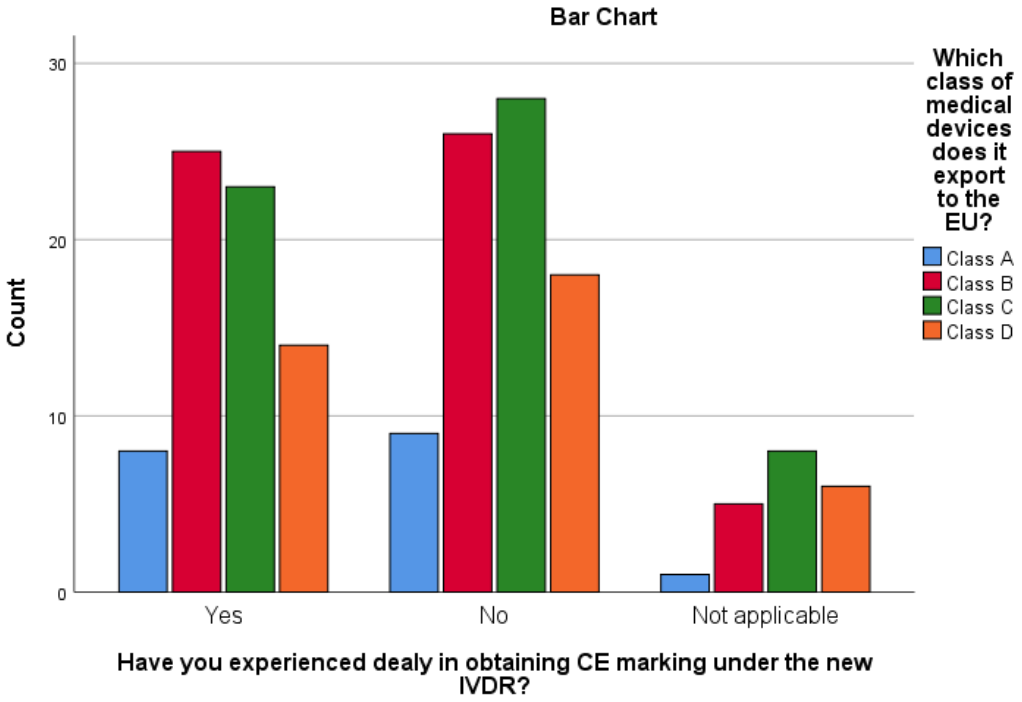
Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.156[a]	6	.905
Likelihood Ratio	2.266	6	.894
Linear-by-Linear Association	1.579	1	.209
N of Valid Cases	171		

a. 2 cells (16.7%) have expected count less than 5. The minimum expected count is 2.11.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.112	.905
	Cramer's V	.079	.905
N of Valid Cases		171	



Have you experienced delay in obtaining CE marking under the new IVDR? * Which class of IVD kits does your organisation manufacture?

Chi-Square Tests

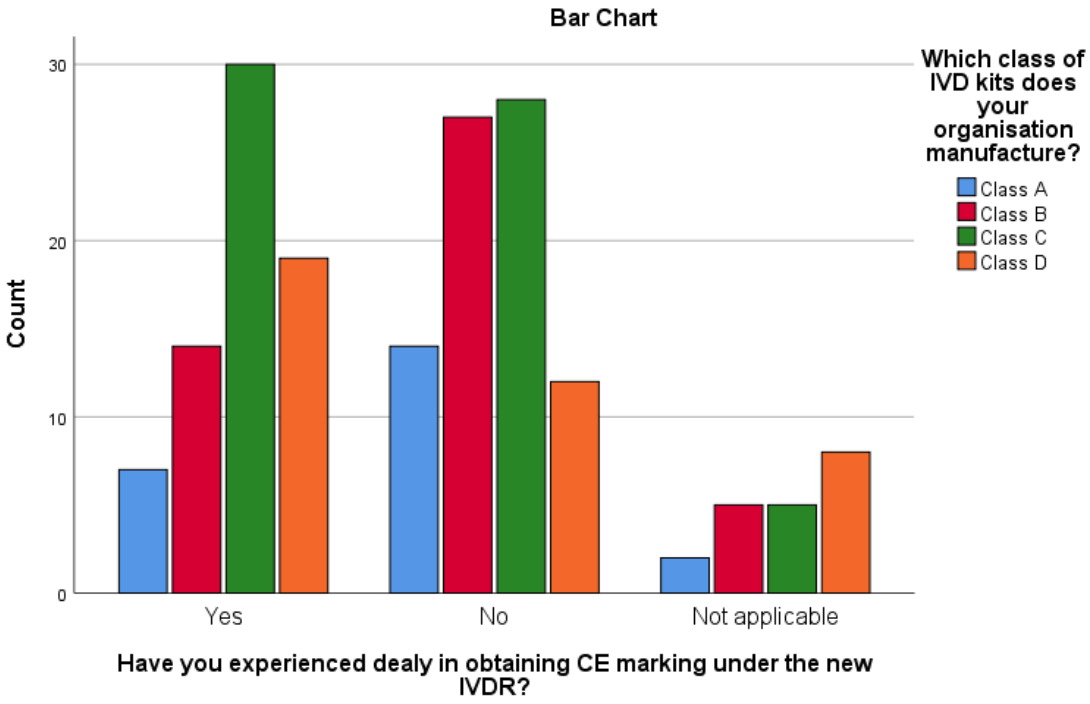
	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	11.194[a]	6	.083
Likelihood Ratio	11.108	6	.085

Linear-by-Linear Association	.789	1	.374
N of Valid Cases	171		

a. 2 cells (16.7%) have expected count less than 5. The minimum expected count is 2.69.

Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Phi	.256	.083
	Cramer's V	.181	.083
N of Valid Cases		171	



Appendix B: Ethics Application & Declaration Form

GRIFFITH COLLEGE

Innopharma education

Ethics Application & Declaration Form

DISSERTATION TITLE: **Regulatory Strategy and Market Access Challenges under EU IVDR 2017/746: A Case Study of Indian IVD Exporters of Rapid Diagnostic Kits.**

RESEARCHER'S NAME: **Adnan Shaikh**

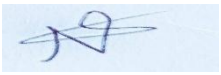
PROGRAMME OF STUDY: **MSc in Medical Device Technology and Business**

SUPERVISOR'S NAME: **Caoimhe Reid**

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College's ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or the ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research. I will reference and/or acknowledge any material or sources used in its preparation, and I will not plagiarise the work of anyone else.

For Student:
STUDENT SIGNATURE:

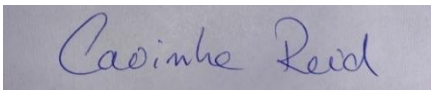


DATE: 24/08/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE:



DATE: 24/08/2025

For Ethics Committee (if required):			
Ethics Committee Approval Given: N/A	Yes	No	☐
ETHICS COMMITTEE MEMBER SIGNATURE: N/A			
DATE: N/A			

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

This study aims to analyse the strategic and regulatory issues that were experienced by Indian exporters of rapid diagnostic kits as a result of the In Vitro Diagnostic Regulation (IVDR) by the European Union (EU IVDR 2017/746). The IVDR succeeds the previous In Vitro Diagnostic Directive (IVDD) with more stringent CE-marking, classification, technical documentation, and requirements regarding its involvement with Notified Bodies. Such changes, especially for exporters in non-member/EU countries such as India, are compelled to improve their regulatory and documentation procedures to retain their access to the EU market.

This study aims to understand how Indian producers of Class D (e.g., HIV test kits) and Class B (e.g., pregnancy kits) diagnostic products have updated their policies to ensure compliance with the mandates of the IVDR. This study examines strategic responses within fields including quality systems, post-market surveillance, and performance evaluation reports. It also evaluates the limitations, like accessibility to Notified Bodies, which is low and resource constraints that complicate the ability of the organisation to achieve CE certification on time.

This study will pursue the following objectives:

- **To investigate** the organisational and strategic changes implemented by Indian IVD manufacturers to comply with EU IVDR 2017/746, particularly in regulatory affairs and quality assurance.

- **To identify** the key compliance challenges—such as access to Notified Bodies, resource limitations, and post-market surveillance (PMS)—encountered during the IVDR transition.
- **To explore** how Indian manufacturers are updating technical documentation, including Performance Evaluation Reports (PERs) and clinical evidence, to align with IVDR.
- **To assess** the impact of IVDR on CE marking timelines and overall EU market accessibility for Indian IVD exporters.
- **To recommend** practical strategies for improving the IVDR compliance readiness of Indian IVD kit manufacturers based on research findings.

1.2 Research methodology:

In this research, to collect both quantitative and qualitative primary data, a survey research study based on a mixed-methodological design will be used. The study is conducted by professionals working with the Indian IVD (In Vitro Diagnostics) sector. The proposed study will gather primary data regarding the perception of these professionals and their reaction to the adoption of EU IVDR 2017/746, specifically impacting CE marking, regulatory documentation, in addition to access to market of rapid diagnostic kits.

The collection of data will be performed through the use of an online survey to be distributed in professional online networks like LinkedIn, email groups, and regulatory forums. A survey will be developed on Google Forms or Microsoft Forms and will include about 15-20 questions. This will encompass both closed-ended (e.g., Likert-scale, multiple-choice) questions to collect structured information on timelines of certification of CE, level of adaptation to regulations, and obstacles to compliance; and open-ended questions to enable respondents to explain in detail their experience, challenges faced and overall strategic responses.

It will involve a purposive sampling strategy whereby those with pertinent experience in Regulatory Affairs, Quality Assurance or Compliance in Indian IVD companies are targeted. Before participants can gain access to the survey, they will be requested to confirm their volunteer role and agree to participate. Refinement of the question structure and usability will be accomplished by conducting a pilot test involving 2-3 professionals.

The survey will be voluntary and anonymous, and all ethical aspects of informed consent, data protection, and the option of withdrawal will be followed. There will be no interviews

or focus groups. The ethics approval will involve presenting the survey questions and consent information in the appendix.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

<u>If you have answered NO to ALL questions, please go straight to Section 4.</u>

<u>If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.</u>

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study

To conduct this research, the population will include professionals with at least two years of employment, in the Indian In Vitro Diagnostic (IVD) manufacturing industry in the field of Regulatory Affairs, Quality Assurance, and Compliance. These people are directly engaged in conducting activities of CE marking, creating technical documentation, communicating with the Notified Bodies, and implementing actions following the regulations of EU IVDR 2017 / 746.

They are chosen since they are best placed to offer and give first-hand insights on how the Indian IVD-based companies are responding to adjustments of their organisational and regulatory approach due to the IVDR. Their expertise is critical in terms of interpreting operational limitations, regulatory preparedness, and access to market predicaments. Only practitioners who are currently employed in IVD-exporter companies will be employed, and students, interns, or persons who do not belong to the regulatory, quality assurance or compliance sectors will be excluded.

4.2 How do you plan to gain access to/contact/approach your participant(s).

The participants shall be contacted using various professional networks, such as LinkedIn, sending out email invitations to industry-specific groups, and use of discussion groups related to IVD professionals. The brief invitation text will introduce the topic of the research, the set of ethical precautions (confidentiality, consent, voluntary participation), and have a direct link to the online survey on Google Forms or Microsoft Forms.

Study participants will also read the Participant Information Letter (PIL) and agree to take part in the survey by checking boxes of agreement. Personal information will not be gathered, and the respondents will be completely anonymous.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

The online survey will start with a Participant Information Letter (PIL). It will give the reason of doing the research, what the participant will be requested to do, the rights the participant has concerning anonymity and withdrawal as well as the contact details of the researcher and the supervisor. Collected information will be kept anonymous and fully confidential.

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

No: my research study involves an online survey only and/or does not require signed consent.

Consent will be obtained by including two tick boxes at the start of the online survey:

- **"I confirm that I have read the Participant Information Letter and understand the purpose of the research."**
- **"I voluntarily consent to participate in the study."**

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Any research information collected will be secured in line with GDPR and Griffith guidelines. The filled survey questionnaires will be screened through Google Forms or Microsoft Forms and will be automatically saved on a password-protected personal drive, accessible only by the researcher. The participants will not have their personal or identifiable information collected.

Raw data will be anonymised and exported to Microsoft Excel to be analysed. Such anonymised files are going to be kept in a limited file and copied to a secondary encrypted device. Evidence shall be stored for up to 2 years once the outcome of the dissertation is certified by the exam board, following which the same shall be deleted permanently. The data will be accessible to the researcher and the project supervisor only. At submission of the dissertation, a copy of the anonymised data will be uploaded to the primary data folder on Moodle as a means of verifying the data.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:
STUDENT SIGNATURE:

DATE: 24/08/2025

Appendix C: Participant Information Letter

"REGULATORY STRATEGY AND MARKET ACCESS CHALLENGES UNDER EU IVDR 2017/746: A CASE STUDY OF INDIAN IVD EXPORTERS OF RAPID DIAGNOSTIC KITS"

I would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Adnan Shaikh, and I am currently pursuing a Master's degree in Medical Device Technology and Business at Griffith College in collaboration with Innopharma Education. This study is part of my dissertation project.

The reason I am undertaking this study is to investigate the responses of the Indian manufacturers of the rapid diagnostic kits (Class B and Class D) to the regulatory requirements that have been brought onboard by the In Vitro Diagnostic Regulation (EU IVDR 2017/746) of the European Union, especially where CE marking and compliance strategies are concerned. The results will help understand more about obstacles and best industry practices for exporters during this regulatory change.

WHAT WOULD TAKING PART INVOLVE?

If you accept to participate, you will be requested to participate in a brief online survey which will consist of multiple-choice, rating and open-ended questions. The questionnaire will consume approximately 15- 20 minutes of your time. The questionnaire is anonymous, and you will not be required to provide any personal, company-sensitive or clinical information.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

The reason you have been invited to take part in the study is that you are an employee who is currently engaged in the Indian IVD (In Vitro Diagnostic) manufacturing sector, namely, in a position associated with Regulatory Affairs, Quality Assurance, or Compliance. Your close participation in such activities as CE marking, technical documentation, and communications with Notified Bodies, in addition, makes your views especially valuable.

Since you have been engaged in this field, the information you have to share will largely help comprehend how Indian exporters of rapid diagnostic kits are surviving the maze of being compliant with EU IVDR 2017/746. I am convinced that an individual with your background can provide special and realistic insights that are needed to meet the goals of this study.

DO YOU HAVE TO TAKE PART?

Please note:

- Participation is completely voluntary.
- You may skip any question you do not wish to respond to.
- You may withdraw from the study at any time before submitting the survey without any significance**.**

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

No risks are foreseen upon participation. The survey asks no personal, financial or health-related information. The research can be of assistance to the broader IVD sector as it can be developed into policy formulation, regulation, or exporter strategy.

WILL TAKING PART BE CONFIDENTIAL?

Yes. The responses to your questions will be anonymous. We will not collect any identifiable information (like your name, organisation or email). Only the summary form of results will be reported. Nevertheless, disclosure might be required of this researcher to the proper authorities in cases with genuine proceeding threats of harm to yourself and others, in rare cases that answers indicate such a course of action.

HOW WILL THE INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

The researcher will store the survey data in a password-protected device, which shall only be accessed by the researcher. IP addresses, emails or names will not be recorded.

Survey data will be anonymised and will be stored in a secure place until after the awarding of my degree. The anonymised data can be held for a maximum of two years after submission. During this time, if you would like to have a copy of the final study, you can contact me, and I would be very happy to share the copy once the final marking process has been completed**.**

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The outcomes will only be utilised to form part of a Master dissertation. The final dissertation will be presented to Griffith College, and it may be deposited in the college library or other online databases so that it may be used as a source of academic reference.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

For further information, please contact:

1. **Adnan Shaikh**
   Email: adnan.shaikh@student.griffith.ie
2. **Caoimhe Reid**
   Email: caoimhe.reid@griffith.ie

Appendix D: Survey Questionnaire

1. Kindly confirm that you have read and understood the purpose of this study

- Yes
- No

2. I voluntarily consent to participate in this study.

- Yes
- No

SECTION A – Eligibility Screening

3. Do you currently work in the Indian In Vitro Diagnostic (IVD) manufacturing industry?

- Yes
- No

4. Do you have at least two years of professional experience in Regulatory Affairs, Quality Assurance or Compliance inside the IVD sector?

- Yes
- No

SECTION B – Participant Background

5. In which area do you work currently?

- Regulatory Affairs
- Quality Assurance
- Compliance management
- Product Management
- Other (please specify): _____

6. How many years of professional experience do you have in the IVD industry?

- 2–5 years
- 6–10 years
- More than 10 years

7. Which class of IVD kits does your organisation manufacture?

- Class A
- Class B
- Class C

- Class D
- Not sure

8. Which class of medical devices does it export to the EU?

- Class A
- Class B
- Class C
- Class D

SECTION C – Organisational & Strategic Adaptations (Aim 1)

9. How equipped is your organisation for IVDR 2017/746 compliance?

- Fully compliant
- Partially compliant
- Not compliant
- In progress

10. Has your organisation conducted any of the following actions in response to IVDR?

- Upskilled existing employees through IVDR-related training
- Hired new employees in regulatory/quality departments
- Restructured internal teams or departments
- Increased budget allocation to compliance
- Other (please specify): _____

11. Have you reorganised your Quality Management System (QMS) to meet IVDR requirements?

- Yes
- No
- In progress
- Not sure
- If "yes" or "In Progress", please briefly describe the work involved in this

12. What new reports or studies were required during the transition from IVDD to IVDR? (Select all that apply)

- Performance Evaluation Reports (PER)

- Post-Market Performance Follow-Up (PMPF)
- Clinical Performance Studies
- Risk Management File
- Other (please specify): _____

13. Which area posed the highest challenge during the transition from IVDD to IVDR?

- Clinical evaluation
- Documentation complexity
- Notified Body delays
- Internal resource limitations
- Other (please specify): _____

14. Has your organisation required outside consultancy to support IVDR compliance?

- Yes
- No
- Not sure

SECTION D – Compliance Challenges & Technical Documentation (Aims 2 & 3)

15. Which key documents have been updated to comply with IVDR? (Select all that apply.)

- Technical Documentation
- Performance Evaluation Report (PER)
- Post-Market Performance Follow-up (PMPF)
- Clinical Evidence Documentation
- Other (please specify):_____

16. Please describe one major regulatory or documentation challenge your company encountered under IVDR.

17. Rate the level of difficulty in accessing a Notified Body for IVDR certification.

- Very easy
- Somewhat easy
- Difficult
- Very difficult
- Not attempted
- Please elaborate on your answer____

18. How effective was communication within your organisation and with external partners (e.g. Notified Bodies, consultants, distributors) during the IVDR transition?

- Very effective
- Moderately effective
- Poor
- Not applicable

19. To what extent has IVDR impacted regulatory costs for your organisation?

- Major increase
- Minor increase
- No impact
- Minor decrease
- Major decrease.

SECTION E – Market Access & Certification Outcomes

20. Have you experienced dealy in obtaining CE marking under the new IVDR?

- If Yes, Please Elaborate
- No
- Not applicable

21. What is the estimated average time taken to get CE marking under IVDR?

- Less than 6 months
- 6–12 months
- Over 12 months
- No CE marking obtained yet

22. Compared to your organisation's past experience with CE marking under the IVDD, how would you describe this timeframe?

- Faster than IVDD
- About the same as IVDD
- Slower than IVDD
- Not sure / No prior IVDD experience

23. How has the IVDR affected your company's international growth or export approaches?

24. What approaches has your organisation implemented to overcome the market entrance barriers in the EU under IVDR?

SECTION F – Perceptions & Strategic Recommendations

25. Do you agree that the EU IVDR 2017/746 increases product safety and market reliability?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

26. In your opinion, what additional regulatory support or changes would be an advantage to Indian IVD manufacturers?
27. What can Indian IVD manufacturers do to increase their readiness for EU IVDR 2017/746 compliance?