ENTREPRENEURSHIP AND COLLABORATIVE INNOVATION IN MEDICAL DEVICES: SMALL AND MEDIUM-SIZED ENTERPRISE COMPETITIVENESS UNDER THE EUROPEAN MEDICAL DEVICE REGULATION

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Abstract

This paper explores how entrepreneurship and collaborative innovation enhance the competitiveness of small and medium-sized enterprises (SMEs) in the European medical device sector under the Medical Device Regulation (MDR 2017/745). It examines the strategic role of multi-stakeholder partnerships (spanning academia, industry, clinicians, and regulators) in navigating regulatory complexities and accelerating innovation. The study highlights how SMEs leverage collaborative ecosystems to meet compliance, improve product quality, and access new markets. Findings suggest that adaptive innovation models and regulatory alignment are critical for sustaining SME growth and competitiveness in a rapidly evolving healthcare landscape.

Keywords

Medical Device Regulation (EU 2017/745); entrepreneurship; collaborative innovation; small and medium-sized enterprises (SMEs); competitiveness; digital twin technology; regulatory compliance; healthcare innovation

I. Introduction

The medical device industry is one of the European Union (EU)'s most dynamic and innovation-driven sectors. Advances in digital health, artificial intelligence (AI), and smart monitoring systems are transforming patient care and creating new opportunities for sustainable healthcare solutions. However, this innovation

landscape has been profoundly reshaped by the implementation of the Medical Device Regulation (EU 2017/745) (MDR), which came into force in May 2021. Designed to enhance safety, traceability, and clinical effectiveness, MDR establishes a stricter regulatory environment that demands greater evidence, robust post-market surveillance, and transparent compliance mechanisms across all types of devices.

While the regulation aims to strengthen the internal market and patient trust, its implementation has raised concerns about the competitiveness of European firms, especially small and medium-sized enterprises (SMEs). SMEs are widely recognized as the primary drivers of disruptive innovation, yet they often face disproportionate burdens under MDR due to limited financial resources, staff expertise, and access to notified bodies (an independent, EU-designated organization accredited to evaluate whether medical devices meet the regulatory, safety, and performance requirements). This dynamic creates a paradox: the very firms most capable of advancing breakthrough technologies may be those most at risk of being slowed down or excluded from the market. At the same time, MDR can also function as a catalyst by setting higher quality benchmarks, enhancing international credibility, and creating incentives for sustainable design. This dual impact, short-term challenges but potential long-term opportunities, frames the central question of how SMEs can adapt and thrive under the new regulatory regime.

In this context, entrepreneurship and collaborative innovation emerge as crucial strategies. Entrepreneurial agility allows SMEs to adapt business models, explore alternative financing mechanisms, and align sustainability with competitiveness. Collaboration (with hospitals, universities, clusters, and European research programs such as Horizon Europe) enables resource-sharing, accelerates regulatory learning, and provides access to essential clinical data. Together, these strategies represent pathways for SMEs to mitigate MDR's short-term burdens while exploiting its long-term opportunities.

In this paper, **e**ntrepreneurship refers to the capacity of SMEs to mobilize resources, design business models, and take calculated risks to bring medical technologies from concept to market under the demanding requirements of MDR (EU 2017/745). Collaborative innovation denotes the joint creation of knowledge, processes, and solutions through partnerships among SMEs, hospitals, research centres, investors, and regulatory actors, enabling smaller firms to access clinical data, share compliance costs, and accelerate evidence generation. Together with these two dimensions, smart and sustainable development is understood as the integration of data-driven, connected, and AI-enabled device capabilities with eco-design and resource-efficient practices across the device life cycle, from design and manufacturing to use and end-of-life.

To ground this analysis, the paper uses the case study of Ventijet Health Technology. The medical devices developed by Ventijet integrate digital twin

technology (a virtual replica of a medical device or patient system that enables real-time monitoring, simulation, and predictive decision-making) and advanced monitoring to optimize ventilation therapies in intensive care units, exemplifying how SMEs pursue both technological excellence and sustainable development in a highly regulated context. To investigate how SMEs can sustain competitiveness under MDR (EU 2017/745), we employ a qualitative case study of Ventijet Health Technology, combining documentary evidence, policy analysis, and industry sources.

The remainder of the paper is organized as follows. Section II reviews literature on entrepreneurship, smart and sustainable development, collaborative innovation, and EU 2017/745. Section III outlines the methodology. Section IV presents the Ventijet analysis. Section V discusses MDR's impact on competitiveness through our tripartite framework. Section VI develops policy and managerial implications. Section VII concludes with contributions, limitations, and avenues for future research.

The central research question of this paper is therefore: How does MDR (EU 2017/745) affect the competitiveness of SMEs in the medical device industry, and in what ways can entrepreneurship and collaborative innovation support smart and sustainable development under these conditions? By combining a review of the literature with in-depth research, this work contributes to understanding the interplay between regulation, innovation, and competitiveness in one of Europe's most strategically important industries.

II. Literature review

A. Entrepreneurship and innovation in medical devices

Entrepreneurship plays a pivotal role in the medical device industry, as startups and small ventures are often the source of disruptive innovation (innovations that create new markets or value networks, often displacing established products or practices). Unlike large corporate manufacturers, which tend to prioritize risk minimization and incremental improvement, startups are better positioned to explore radical technologies (high-impact technologies that fundamentally alter existing medical device paradigms, introducing entirely new capabilities) such as AI-driven monitoring systems, connected devices, or digital twin applications [1,2]. The entrepreneurial capacity to quickly prototype, test, and adapt products allows smaller companies to identify unmet clinical needs and translate them into novel solutions with greater speed than established incumbents.

However, entrepreneurship in medical devices faces substantial barriers due to the regulatory intensity of the sector. Unlike in digital or consumer technologies, where "trial and error" innovation is feasible, medical devices demand rigorous

safety validation and regulatory approval before commercialization [3]. This tension means that startups often rely on collaborative innovation networks, including partnerships with hospitals, universities, and accelerators, to bridge gaps in resources, expertise, and compliance knowledge [4].

Corporate firms, by contrast, maintain a focus on incremental innovation (step-by-step improvements to existing devices, enhancing performance or usability without changing the core concept) and product line extensions, seeking to safeguard established market shares. Evidence from ventilator and monitoring device markets demonstrates that major corporations such as Dräger, Philips, or Getinge invest heavily in process optimization and incremental improvements, while more disruptive developments, such as AI-powered ventilation support, tend to emerge from SMEs and startups [5]. This dual innovation dynamic underscores the importance of entrepreneurship as the driver of technological renewal in the medical device sector.

B. Smart and sustainable development in healthcare

In recent years, the medical device industry has increasingly integrated the principles of smart technology and sustainability into innovation strategies. Smart devices, including predictive monitoring systems, AI-enabled decision support tools, and cloud-based analytics platforms, enhance clinical outcomes by providing real-time data insights, improving diagnostic precision, and supporting tailored patient management [6]. The introduction of digital twins (virtual models of a patient's physiology) illustrates this shift toward individualized, data-driven care [7].

Alongside smart functionality, sustainability has become a critical dimension of competitiveness. Medical devices contribute significantly to healthcare's environmental footprint, prompting increased attention to eco-friendly materials, energy-efficient manufacturing processes, and circular economy principles such as reuse, refurbishment, and recycling [8]. The European Green Deal and the EU's Circular Economy Action Plan reinforce these expectations, creating pressure on device manufacturers to align with environmental, social, and governance (ESG) objectives [9].

Startups and SMEs are particularly well-placed to lead this transition. Their flexible structures enable the integration of sustainable design early in product development, while digital technologies, such as Internet of Things (IoT), enable monitoring or cloud-based data analysis, improving both patient outcomes and system-level resource efficiency [10]. Smart and sustainable development is therefore not only a response to societal and policy pressures but also a potential source of competitive advantage in an increasingly demanding regulatory and market environment.

C. Collaborative innovation

The complexity of medical device development makes collaborative innovation essential. Collaborative innovation refers to the process by which firms, hospitals, universities, and public agencies share knowledge, infrastructure, and resources to accelerate product development and reduce costs [11]. This is especially critical in the context of MDR, where generating robust clinical evidence and building regulatory-compliant systems often exceeds the capacity of individual SMEs.

Clusters and consortia play a central role in facilitating collaboration. For example, the Basque Health Cluster in Spain provides a platform for SMEs, startups, hospitals, and universities to share expertise and build synergies in health technologies. At the European level, Horizon Europe programs and European Institute of Innovation and Technology (EIT Health) initiatives foster cross-border collaborations, supporting joint R&D, access to funding, and regulatory learning. Such networks lower the barriers to entry for SMEs and accelerate the adoption of disruptive technologies in clinical environments [12].

Hospital-industry partnerships represent another vital form of collaborative innovation. By involving clinicians early in the design and testing of devices, companies gain access to real-world data, user feedback, and clinical validation pathways that are otherwise difficult to obtain. These partnerships not only improve product-market fit but also generate the clinical evidence necessary for MDR compliance. In this sense, collaborative innovation is both a practical necessity and a strategic asset for SMEs seeking to remain competitive under the new regulatory paradigm.

D. MDR (EU 2017/745): Overview and implications

The MDR (EU 2017/745) introduced one of the most significant regulatory overhauls in the European health technology sector in decades. Its key features include:

- Stricter classification rules covering software, digital health, and connected devices;
- Enhanced clinical evaluation requirements, mandating robust evidence and post-market surveillance;
- CE marking (the certification mark indicating that a medical device complies with MDR safety, performance, and regulatory requirements) requirements tied to comprehensive conformity assessments;
- Greater transparency through the EUDAMED (the European Database on Medical Devices, designed to centralize information on device registration, clinical investigations, and vigilance) database and Unique Device Identification (UDI), which is a standardized system for uniquely identifying medical devices, improving traceability and post-market safety.

The benefits of MDR are clear: improved patient safety, harmonized standards across member states, and increased trust in European-made devices [13]. However, MDR also creates substantial challenges: certification timelines have lengthened, costs have escalated, and the number of designated notified bodies has decreased, creating bottlenecks [14]. These issues disproportionately affect SMEs, which face difficulty securing regulatory expertise, financing clinical trials, and absorbing the delays in time-to-market [15]. Thus, MDR is a double-edged sword: while it strengthens Europe's reputation for quality and safety, it simultaneously risks undermining SME competitiveness if adaptation mechanisms are not adequately supported.

E. Competitiveness and SMEs

Literature consistently highlights SMEs as the most vulnerable actors under MDR. Studies show that smaller firms often experience reduced innovation speed, delayed product launches, and financing pressures linked to the regulatory changes [16]. In particular, the requirements for continuous post-market surveillance and the generation of clinical evidence impose an especially heavy burden. Unlike large corporations, which benefit from established regulatory departments, extensive networks, and experienced multidisciplinary teams, SMEs typically lack the internal structure, expertise, and resources to sustain these obligations. This asymmetry can result in strategic setbacks for smaller firms, including product withdrawals or complete market exits [17].

Nevertheless, research also points to strategic pathways by which SMEs can remain competitive. Collaborative approaches (such as joint ventures with hospitals, participation in EU-funded projects, or partnerships within health clusters) allow smaller firms to pool resources and knowledge [12]. SMEs that integrate sustainability and smart technologies into their designs may also differentiate themselves competitively, appealing to hospitals and regulators prioritizing safety, efficiency, and environmental impact [10].

In this sense, MDR does not solely represent a barrier; it also provides an opportunity for SMEs to professionalize operations, align with sustainability goals, and strengthen international competitiveness. The illustration of Ventijet Health Technology, analysed in this paper, exemplifies how entrepreneurial ventures can leverage innovation and collaboration to overcome regulatory challenges and sustain competitiveness in a highly regulated sector.

III. Methodology

A. Research approach

This study adopts a qualitative case study methodology, which is particularly suited to exploring complex, context-dependent phenomena such as the impact of regulatory frameworks on innovation and competitiveness. The case study method allows for in-depth analysis of both organizational processes and external environmental pressures, offering insights into how SMEs adapt their strategies in response to the MDR (EU 2017/745).

A case study also enables the integration of multiple data sources (documentary evidence, policy frameworks, and market intelligence) into a coherent analysis [18]. The research examined entrepreneurship and innovation in smart and sustainable medical devices. The present study deepens the investigation into how entrepreneurial and collaborative strategies can mitigate the regulatory challenges faced by SMEs in the European medical device sector.

B. Case selection rationale

The selected example, Ventijet Health Technology and its medical device portfolio, represents a paradigmatic example of SME-led innovation under MDR constraints. Ventijet is a small, innovation-driven company specializing in respiratory care devices, whose flagship product leverages digital twin technology and advanced monitoring to optimize ventilation therapies in intensive care units.

This model was chosen for three reasons:

- SME context – Ventijet Health Technology reflects the characteristics of many European SMEs in the medical device industry: highly innovative, resource-constrained, and disproportionately affected by MDR's requirements;
- Technological novelty – The product portfolio exemplifies the integration of smart technologies (AI, predictive modeling, and real-time monitoring) and sustainability goals, both of which are increasingly relevant in the industry;
- Regulatory relevance – As a product portfolio covering different medical devices of varying risk levels, scopes, and intended uses under MDR, the medical devices must undergo rigorous conformity assessment, clinical evaluation, and certification procedures. This makes it a strong example to examine how SMEs navigate MDR's hurdles while striving for competitiveness.

C. Data sources

To ensure triangulation and validity, the analysis draws from a combination of primary and secondary sources:

- Thesis data: Project documentation, technical specifications of the medical device portfolio, and prior analyses of Ventijet Health Technology's business and regulatory strategy;
- Regulatory documents: MDR (EU 2017/745), Medical Device Coordination Group (MDCG) guidance, and European Commission policy papers;
- Market reports: Industry analysis on the medical device sector, focusing on smart and sustainable innovations, investment trends, and MDR's market impact (e.g., MedTech Europe reports, Frost & Sullivan);
- Academic literature: Peer-reviewed studies on entrepreneurship, collaborative innovation, and regulatory adaptation in medical devices;
- Policy papers: EU Horizon Europe program documents, position papers from MedTech Europe, and open letters to the European Commission concerning SME challenges under MDR;

This mixed evidence base provides a comprehensive understanding of the demonstration, capturing both firm-level dynamics and system-level regulatory pressures.

D. Analytical framework

The competitiveness of SMEs under MDR is analysed through a framework structured around three key axes:

1. Innovation Capacity (Technological and Business Model Innovation):
- Examine the extent to which SMEs like Ventijet Health Technology can develop and integrate smart and sustainable technologies (e.g., digital twin, predictive monitoring).
- Considers business model innovations such as subscription-based services, equipment leasing, and partnerships with healthcare providers;

2. Regulatory Adaptation (Compliance with MDR):
- Analyzes the strategies employed to meet MDR's stringent requirements: clinical evidence generation, notified body interactions, CE marking, and post-market surveillance;
- Evaluates the balance between regulatory burden (time, cost, expertise) and competitive advantage (trust, safety, international market access);

3. Entrepreneurial Strategies (Collaboration, Investment, Sustainability):
- Investigates how SMEs leverage entrepreneurial practices to overcome resource constraints;
- Focuses on collaboration with hospitals, clusters, and EU research programs to share knowledge and resources;
- Reviews investment strategies, including venture capital, industrial partnerships, and public funding, as well as the integration of sustainability practices as differentiators in competitive positioning.

This tripartite framework enables a structured assessment of how SMEs can sustain competitiveness by linking entrepreneurial agility, collaborative innovation, and regulatory adaptation within the evolving European medical device landscape.

IV. Case study: Ventijet Health Technology

A. Background

Ventijet Health Technology is a European SME founded in 2020 and dedicated to the design and development of medical devices for respiratory care. With a lean team of around ten core members (bringing together expertise in intensive care medicine, biomedical and industrial engineering, and regulatory affairs) Ventijet reinforces its capabilities through specialist advisors and strategic partnerships with hospitals, research groups, and industrial collaborators. Planned new hires in software, artificial intelligence, and business development further strengthen its multidisciplinary profile.

Founded with the mission of advancing intensive care and monitoring technologies, Ventijet exemplifies how entrepreneurial firms can drive innovation in highly regulated environments. Its projects represent a breakthrough in critical care by enabling predictive and personalized ventilation management through digital twin technology and advanced data analytics. Conceived to address the pressing clinical challenge of improving patient outcomes in mechanical ventilation while reducing ventilator-induced complications, the systems combine real-time monitoring with predictive modelling to deliver actionable insights to clinicians, thereby enhancing evidence-based decision-making in Intensive Care Units (ICUs).

The regulatory roadmap for Ventijet's products follows MDR (EU 2017/745) pathways applicable to advanced ventilators and software-driven monitoring devices. Key milestones include (Fig. 1):

(i) Design and risk management under ISO 13485 (the international standard for quality management systems specific to medical devices, required under MDR (EU 2017/745)) Quality Management System (QMS) (an organizational framework of processes and procedures ensuring compliance, safety, and continuous improvement in device development and commercialization);

(ii) Usability testing and pre-clinical bench validation;

(iii) Ongoing clinical trials at hospitals, with early results indicating up to 25% improvement in oxygenation and lung recruitment in acute respiratory distress syndrome (ARDS) patients;

(iv) Preparation of clinical evaluation reports and notified body engagement for CE marking, targeted for 2027–2028;

(v) implementation of post-market surveillance (PMS) and periodic safety update reports (PSUR) after market entry.

Ventijet faces concrete challenges typical of SMEs under MDR: limited access to notified bodies, high costs of generating compliant clinical evidence, reliance on public funding mechanisms, and the need to align hospital collaborations with regulatory timelines. These hurdles, while significant, have also driven the company toward greater professionalization, cross-border partnerships, and the integration of sustainability and AI-driven design as strategic differentiators. This positioning makes Ventijet a paradigmatic case for exploring how SMEs navigate the dual challenges of competitiveness and MDR compliance.

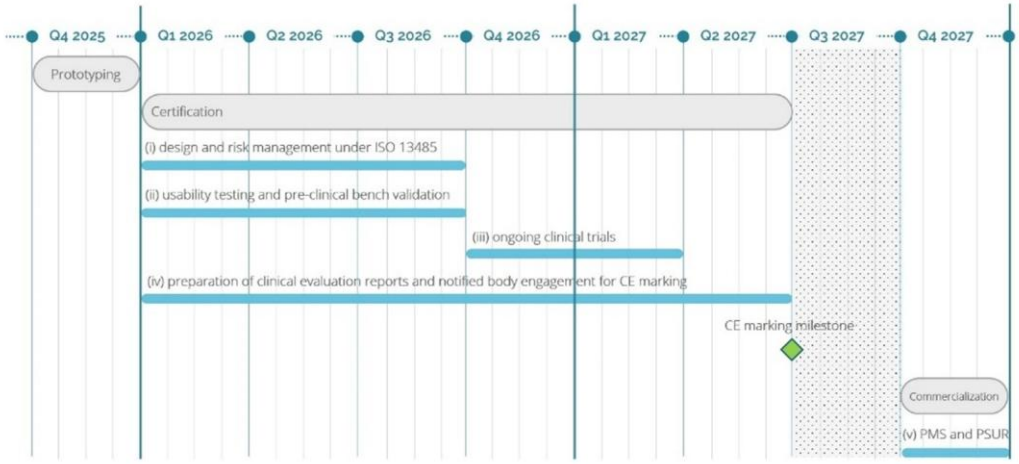

Fig. 2. Ventijet's regulatory product certification roadmap example

B. Technological innovation

At the core of the products is their digital twin model of the patient's lungs, which allows for continuous simulation of respiratory mechanics. This enables: (a) real-time adaptation of ventilation strategies to patient-specific needs; (b) early detection of complex respiratory patterns, such as asynchronous breathing or abnormal pressure dynamics; (c) monitoring multiple parameters, extending beyond the capabilities of conventional ventilators.

This technological innovation aligns with the broader trend of smart healthcare systems, where artificial intelligence, predictive analytics, and IoT-enabled devices converge to enhance clinical practice. Importantly, the product portfolio not only improves patient safety but also contributes to resource efficiency, as more precise monitoring reduces unnecessary interventions and supports sustainability in critical care.

C. Business model innovation

Ventijet's innovation extends beyond technology into its business model strategy. Recognizing that hospitals often face budget constraints and risk aversion toward novel technologies, the company developed flexible access models:

- Subscription-based services, allowing hospitals to access patients' data analytics and cloud monitoring without prohibitive upfront costs;
- Leasing models for equipment, lowering financial barriers to adoption;
- Collaborative partnerships with healthcare institutions, enabling early validation, co-development, and shared learning on product deployment.

These entrepreneurial strategies not only mitigate financial constraints but also facilitate faster market penetration by aligning with hospitals' procurement realities. They also reflect a broader shift in the medical device industry toward servitization, where value is increasingly tied to ongoing services and data-driven insights rather than one-off equipment sales.

D. Regulatory roadmap MDR (EU 2017/745)

Under the MDR (EU 2017/745), medical devices are classified into four categories according to the level of risk they pose to patients and users: Class I (low risk, e.g. non-invasive instruments), Class IIa (moderate risk, e.g. dental fillings, infusion pumps), Class IIb (higher risk, e.g. anaesthesia machines, long-term invasive devices), and Class III (highest risk, e.g. implantable defibrillators, ventilators, cardiovascular stents). The regulatory pathway is progressively more demanding as the device class increases. While Class I devices may follow a self-certification route, Classes IIa, IIb, and III require formal conformity assessment by a notified body. This tiered structure means that the regulatory effort, cost, and timelines are substantially different depending on the class of device a company seeks to commercialize. For SMEs, targeting higher-risk classes typically entails a disproportionately high compliance burden compared to larger corporations with dedicated regulatory infrastructures.

Products in the portfolio, such as Class IIa, Class IIb and Class III under MDR (EU 2017/745), the products face stringent regulatory requirements. Compliance involves:

- CE marking through conformity assessment with a notified body;
- Comprehensive clinical evaluation requiring robust clinical data and validation trials;
- Post-market surveillance systems, including real-world evidence collection and risk management updates;
- Appointment of a Person Responsible for Regulatory Compliance (PRRC) to assess quality and safety documentation.

For SMEs like Ventijet, the MDR introduces significant challenges. The cost of clinical trials, the limited availability of notified bodies, and the extended certification timelines increase both financial and operational pressures. Delays in CE marking also postpone revenue generation, heightening the importance of external financing. Nonetheless, MDR compliance also enhances trust and international competitiveness, as meeting EU standards facilitates recognition in global markets.

E. Financing and investment

To sustain innovation and achieve regulatory compliance, Ventijet has structured an ambitious investment strategy. The company has pursued a financing round of approximately €4 million, combining:

- Venture capital funding to secure long-term growth and scaling capacity;
- Industrial partnerships with established players to leverage expertise and market access;
- Public funding mechanisms, such as Horizon Europe grants, national innovation programs, and regional support schemes.

These funding sources are critical to covering the high upfront costs of MDR compliance, including clinical evidence generation, regulatory consultancy, and certification fees. They also allow Ventijet to build collaborative projects with hospitals and research institutions, directly contributing to MDR requirements for clinical data and post-market validation.

F. Synthesis: MDR impact on Ventijet Health Technology

The Ventijet case illustrates the dual impact of MDR on SMEs:

1. Challenges:
   - Significant increases in compliance costs;
   - Regulatory bottlenecks and certification delays;
   - Heightened financing pressures in the pre-market phase;
2. Opportunities:
   - Strengthened trust and credibility through compliance with one of the world's strictest regulatory frameworks;
   - Enhanced international competitiveness, as MDR certification is often recognized globally;
   - Reinforcement of professionalization and collaboration, pushing SMEs to adopt structured regulatory, clinical, and sustainability strategies.

Through entrepreneurial agility, collaborative partnerships, and smart business models, Ventijet demonstrates how SMEs can navigate regulatory burdens without

compromising innovation capacity. This demonstration underscores the importance of aligning entrepreneurship, sustainability, and collaboration to sustain competitiveness in the European medical device industry.

V. Analysis and discussion

A. Impact of MDR on competitiveness

The introduction of MDR (EU 2017/745) has reshaped the competitive landscape of the European medical device industry. From a barriers perspective, the regulation has resulted in longer time-to-market due to extended conformity assessments, additional requirements for clinical evidence, and limited notified body capacity [13]. For SMEs, these bottlenecks often translate into delays in commercialization and a heavier dependence on external financing to sustain operations during regulatory processes. The cost of compliance, including clinical trials, regulatory consultancy, and post-market surveillance, is also disproportionately burdensome for smaller firms [14].

At the same time, MDR creates important opportunities. By raising quality and safety standards enhances patient and clinician trust in European-made devices. This increased trust may support internationalization, as MDR-certified devices often enjoy smoother entry into non-EU markets due to the regulation's global recognition. Moreover, stricter documentation and transparency requirements push companies to adopt more robust quality management systems, thereby improving long-term competitiveness and resilience. Thus, while MDR initially slows innovation and imposes high costs, it can also act as a driver of professionalization, quality, and international credibility.

B. SMEs vs. corporates

The impact of MDR differs substantially between large corporates and SMEs. Large corporations, such as Philips or Dräger, generally adopt a conservative and incremental innovation approach, favouring product line extensions or efficiency improvements rather than disruptive innovation [5]. Their extensive regulatory departments, financial reserves, and established relationships with notified bodies enable them to absorb MDR requirements with relatively less disruption. In contrast, SMEs are agile, disruptive innovators, often focusing on breakthrough technologies that address unmet clinical needs. However, they face significant resource constraints in terms of regulatory expertise, financing capacity, and staff. MDR slows SMEs by extending development timelines and increasing costs, but it simultaneously forces stronger professionalization, pushing them to adopt structured quality management systems, compliance strategies, and collaborative

networks. Relating to Ventijet, the need to navigate MDR accelerated the establishment of formal regulatory roadmaps and funding strategies that strengthened the company's organizational maturity.

This dynamic suggests that MDR may unintentionally favor corporates in the short term, but SMEs that successfully adapt may become more competitive in the long run due to their dual capacity for agility and professionalized compliance.

C. Role of entrepreneurship

Entrepreneurship is central to sustaining SME competitiveness under MDR. Given the high uncertainty and regulatory burden, SMEs must adopt lean development approaches, and minimise costs while focusing resources on high-value innovations. Flexible business models, such as subscription-based services or equipment leasing, enable SMEs to align more closely with hospital purchasing realities and lower the barriers to adoption. Niche targeting allows SMEs to focus on specific patient segments or clinical needs, avoiding direct competition with corporates that dominate broader markets.

The case of Ventijet demonstrates how entrepreneurial strategies combine technological innovation with financial and market strategies. By integrating digital twin technology, Ventijet introduced a disruptive clinical tool, while simultaneously designing an investment plan of €4 million to cover compliance costs and clinical validation. The company also pursued collaborative partnerships with hospitals to both validate its technology and generate MDR-compliant clinical evidence. This highlights how entrepreneurship in medical devices is not limited to technical creativity but extends to strategic financing, collaboration, and market positioning.

D. Collaborative innovation

The evidence shows that SMEs rarely succeed in isolation under MDR; instead, collaborative innovation is essential. Horizon Europe and other EU programs provide structured frameworks for SMEs to partner with universities, research centers, and other companies, allowing them to share R&D costs and access regulatory expertise. Participation in national and regional clusters, such as the Basque Health Cluster, also fosters synergies by creating ecosystems of SMEs, corporates, and healthcare institutions working toward common innovation goals.

Hospitals play a particularly important role as co-developers and early adopters. Their involvement in device development provides SMEs with real-world feedback, early clinical validation, and the clinical data required for MDR compliance. For Ventijet, partnerships with hospitals were central not only to testing the products but also to building the clinical evidence base necessary for CE certification.

Collaborative data-sharing is another critical component. MDR's emphasis on post-market surveillance and real-world evidence generation requires robust data flows, which are best achieved through collaborative networks involving hospitals, regulators, and industry actors. SMEs that embed themselves in such networks gain both compliance advantages and reputational legitimacy.

E. Sustainability dimension

Although MDR does not explicitly target environmental outcomes, it indirectly promotes sustainability by mandating detailed lifecycle documentation, traceability, and transparency. These requirements encourage companies to better understand the environmental and social impacts of their products, aligning with broader EU policies such as the European Green Deal and the Circular Economy Action Plan [9].

For SMEs, sustainability can become a competitive differentiator. By integrating eco-design principles, resource-efficient production methods, and smart monitoring that optimizes hospital resource use, SMEs can position themselves not only as compliant but also as forward-looking partners for hospitals seeking both safety and sustainability. Ventijet's products, for example, improve clinical efficiency and reduce unnecessary interventions, indirectly contributing to sustainable healthcare practices by optimizing resource utilization in intensive care. Thus, sustainability is not just a regulatory by product but a strategic lever that SMEs can use to stand out in a competitive, compliance-heavy market.

F. Novelty and contribution

Beyond documenting MDR (EU 2017/745)'s frictions, our contribution is a tripartite, SME-oriented framework that links (1) innovation capacity (smart functionality, sustainability by design), (2) regulatory adaptation (clinical evidence, post-market surveillance, notified body engagement), and (3) entrepreneurial strategies (servitized business models, collaborative R&D, blended finance). The Ventijet case operationalizes this framework and demonstrates how combining these levers can convert compliance into a credible market signal and a competitive moat for SMEs.

G. Limitations

This study relies on a single, in-depth case, which may limit external validity. While the example is theoretically informative, cross-case variation (e.g., device class, software as a medical device, disposables vs. capital equipment, market maturity) may produce different adaptation patterns. Data are primarily documentary and secondary; future work should triangulate with interviews (clinicians, notified

bodies, investors) and multi-case comparisons to assess generalizability across EU regions and device categories.

VI. Policy and managerial implications

The findings of this study highlight the dual nature of MDR (EU 2017/745) for the competitiveness of SMEs: while the regulation imposes significant barriers in terms of cost, time, and complexity, it also generates opportunities through improved quality standards, trust, and international recognition. To ensure that SMEs can continue to contribute to the European medical device industry's innovation capacity, both policy-level measures and firm-level strategies are required.

The main policy implications of the presented study are as follows:

- Support for SME adaptation - Policymakers should recognize that SMEs face disproportionate burdens in complying with MDR. Public support mechanisms (such as targeted grants, subsidized regulatory consultancy, and fast-track approval pathways for high-priority innovations) can alleviate financial and administrative pressures. These measures are particularly important for devices addressing unmet clinical needs, such as advanced ventilatory monitoring systems.
- Expansion of notified body capacity - One of the most critical bottlenecks under MDR is the shortage of accredited notified bodies. Expanding capacity through accelerated designation of new bodies and harmonized training for auditors would reduce approval delays, benefiting SMEs that cannot afford prolonged time-to-market.
- Bridging measures and proportionality - Policymakers should consider proportional regulatory requirements for SMEs without lowering safety standards. For example, reducing documentation redundancies, harmonizing interpretations across notified bodies, and extending transitional periods for SMEs would help balance innovation with compliance.
- Promotion of collaborative ecosystems - EU and national governments should further incentivize clusters, consortia, and hospital-industry partnerships. Horizon Europe, EIT Health, and national cluster programs already provide valuable platforms, but dedicated SME-focused instruments within MDR implementation could enhance their impact.
- Integration of sustainability into MDR framework - Future revisions of MDR could explicitly integrate environmental sustainability into regulatory assessments, reinforcing alignment with the European Green Deal. For SMEs, this would create incentives to adopt eco-design and lifecycle management as part of regulatory compliance, turning sustainability into a recognized competitive factor.

Furthermore, the main implications of the present research in the managerial field are synthesis in the following:

- Early integration of regulatory strategy - For SMEs, regulatory compliance must be treated as an integral part of product development rather than a post-hoc process. Ventijet's roadmap illustrates the importance of embedding MDR planning into the design, testing, and financing stages of innovation.
- Entrepreneurial business models - SMEs should adopt flexible business models that mitigate market-entry barriers, such as subscription-based services, equipment leasing, or pay-per-use models. These approaches reduce hospitals' procurement risks and accelerate adoption, creating early revenue streams to offset regulatory delays.
- Collaboration as a survival and growth strategy - Managerial teams should actively pursue partnerships with hospitals, universities, and industry clusters to pool resources, access clinical data, and share compliance knowledge. Collaborative innovation not only lowers costs but also enhances legitimacy and credibility with regulators and investors.
- Financing and investor engagement - MDR compliance is capital-intensive. SMEs must proactively design investment strategies that combine venture capital, industrial alliances, and public funding. Communicating MDR readiness and long-term regulatory resilience can strengthen investor confidence and attract strategic partners.
- Sustainability as differentiator - Managers should leverage eco-design, smart monitoring, and resource-efficient practices not only as compliance necessities but also as marketing and positioning tools. By aligning with hospital sustainability goals and EU policy priorities, SMEs can turn sustainability into a competitive advantage.

In addition to the above-mentioned aspects, the analysis demonstrates that MDR does not inevitably reduce SME competitiveness. Rather, its impact depends on the interplay between policy frameworks that alleviate disproportionate burdens and managerial strategies that transform compliance into an opportunity. The Ventijet case shows that with the right combination of entrepreneurship, collaboration, and sustainability, SMEs can overcome the initial barriers of MDR and position themselves as agile innovators capable of shaping the future of smart and sustainable healthcare.

VII. Conclusions

MDR (EU 2017/745) reshapes European Medtech competitiveness by raising evidentiary standards and post-market obligations. For SMEs, this produces near-term frictions (longer time-to-market, higher costs, and constrained access to notified bodies) but it also strengthens long-term positioning through quality

signalling, international credibility, and organizational professionalization. This dual impact highlights the paradox at the heart of the regulation: it can slow down resource-constrained innovators in the short run, yet it may simultaneously enhance the resilience and reputation of those able to adapt.

The comparative dynamics between corporates and SMEs underscore this paradox. Large firms, with greater resources and dedicated compliance teams, can absorb MDR requirements more easily, but often pursue incremental innovation. SMEs, though more vulnerable to regulatory strain, show agility and disruptive potential; MDR pressures them toward greater professionalization and strategic sophistication. Importantly, while sustainability is not an explicit objective of MDR, the regulation indirectly fosters it through lifecycle documentation, transparency, and post-market obligations (opening a pathway for SMEs that integrate eco-design and resource-efficient practices to convert compliance into a competitive advantage).

The case of Ventijet Health Technology illustrates how entrepreneurship and collaborative innovation can mitigate regulatory barriers while turning compliance into a platform for sustainable growth. By mobilizing resources creatively, forging partnerships with hospitals and research institutions, and embedding sustainability and digital intelligence into device design, SMEs can navigate MDR without losing sight of competitiveness.

The main limitation of this study is that it relies on a single case, which constrains the extent to which findings can be generalized. Outcomes may vary depending on device class, technology type, or market maturity.

The novelty of this paper lies in its development of a tripartite framework (linking innovation capacity, regulatory adaptation, and entrepreneurial strategies) specifically tailored to SMEs operating under MDR (EU 2017/745). This framework moves beyond descriptive accounts of MDR's impact by offering a structured lens through which managers and policymakers can transform compliance from a burden into a strategic asset. Future research should test and refine this framework across multiple SME comparison and device types to identify boundary conditions and generate actionable design rules for sustaining competitiveness under the evolving European regulatory regime.

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