

Strategic Adaptation and Sustainable Growth in Indonesia's Medical Device Industry: A PESTEL-Based Conceptual Analysis of Industry Dynamics and Firm-Level Capabilities

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Abstract

Indonesia's medical device industry has become a strategically important sector in which healthcare demand expansion, import dependence, domestic-content policy, procurement reform, regulatory complexity, and macroeconomic uncertainty jointly shape firm-level competitiveness. This study aims to develop a conceptual framework explaining how medical device firms in Indonesia adapt strategically to external industry pressures in order to achieve sustainable growth. The study employs qualitative document analysis supported by PESTEL-based strategic synthesis. PESTEL refers to the analysis of political, economic, social, technological, environmental, and legal factors affecting the industry. The analysis is grounded in strategic market management, dynamic capability theory, market orientation, the resource-based view, and sustainable marketing. The synthesis indicates that Indonesia's medical device industry continues to provide substantial growth opportunities through public healthcare financing, hospital modernization, primary-care strengthening, and recurring demand for diagnostic, monitoring, and consumable products. However, these opportunities coexist with structural constraints, including reliance on imported high-technology devices, exchange-rate exposure, uneven domestic production capability, local-content compliance requirements, procurement selectivity, and the increasing strategic importance of service reliability. This study contributes to strategic marketing and management literature by proposing a PESTEL–dynamic capability framework that explains how macro-environmental pressures are translated into sensing, seizing, transforming, and sustaining capabilities. Practically, the study suggests that Indonesian medical device firms should align strategy with Domestic Component Level policy, public procurement reform, financial resilience, digital readiness, supply-chain localization, regulatory intelligence, and after-sales service differentiation. Future empirical studies are needed to validate the proposed framework through interviews, surveys, multiple-case studies, or structural equation modelling.

Keywords : Strategic Adaptation; Sustainable Growth; Medical Device Industry; PESTEL Analysis; Dynamic Capabilities; Domestic Component Level.

1. INTRODUCTION

The medical device industry is a strategically important component of the healthcare economy because it connects technological innovation, public health capacity, industrial development, and firm-level competitiveness. Unlike ordinary consumer markets, the medical device sector is highly regulated and institutionally driven. Product safety, clinical reliability, distribution permits, procurement procedures, maintenance capability, calibration, warranty, and after-sales service are central to competitive performance. From the perspective of strategic market management, firms must continuously evaluate external environments, customer needs, competitor behavior, internal resources, and implementation capabilities to sustain competitive advantage (Aaker & Moorman, 2018; Porter, (2023).

Indonesia provides a highly relevant and urgent context for examining strategic adaptation and sustainable growth in the medical device industry. The country's healthcare system continues to expand through public hospitals, private hospitals, primary-care facilities, laboratories, and public health programs. In this article, Badan Penyelenggara Jaminan Sosial Kesehatan (BPJS Kesehatan) refers to Indonesia's

Social Security Administering Body for Health, which plays a central role in financing healthcare utilization. Consequently, demand for medical devices is shaped not only by clinical need but also by institutional procurement, public financing, hospital modernization, primary-care strengthening, and national health-policy priorities.

The scale and trajectory of the Indonesian medical device market illustrate the significance of this issue. Market estimates reported in the original article indicate that Indonesia's medical device market increased from approximately USD 4.38 billion in 2023 to USD 4.78 billion in 2024, with a projected compound annual growth rate (CAGR) of 9.1% for 2024–2030 (Nexdigm, 2025). Consumables and disposables accounted for around 35% of the market in 2024, while public hospitals contributed approximately 40% of device revenues, reflecting the central role of public-sector healthcare demand and institutional procurement in shaping market opportunities (Nexdigm, 2025). These figures indicate that Indonesia's medical device market is not only growing commercially, but is also becoming increasingly important in the broader context of health-system transformation and industrial development.

However, market growth does not automatically guarantee sustainable firm performance. Indonesia's medical device industry remains constrained by structural dependence on imports, exchange-rate volatility, technological gaps, procurement selectivity, and regulatory change. The (U.S. International Trade Administration, 2025) reported that Indonesia's medical device trade deficit could reach approximately USD 1.45 billion in 2025, indicating that domestic demand remains closely linked to imported technology, foreign-currency exposure, and global supply-chain vulnerability. At the same time, domestic production is projected to rise from approximately USD 2.12 billion in 2020 to USD 3.37 billion in 2025, suggesting progress in local manufacturing capacity, although advanced medical technologies such as magnetic resonance imaging, computed tomography scanners, robotic surgery systems, and complex diagnostic equipment remain difficult to localize (U.S. International Trade Administration, 2025).

The urgency of strategic adaptation is further reinforced by healthcare financing and public-sector budget allocation. Reports on the 2026 health transformation budget show an allocation of approximately IDR 128.5 trillion for the health sector, including about IDR 59 trillion for BPJS Kesehatan support, IDR 31.1 trillion for hospital services, IDR 24.5 trillion for primary care, IDR 9.7 trillion for priority health programs, and IDR 2.5 trillion for medical education (Antara, 2025); InvestorTrust, 2025). This funding structure demonstrates that medical device demand is likely to remain concentrated in institutional healthcare segments, particularly public hospitals, referral hospitals, primary-care facilities, and government-supported health programs. Therefore, firms operating in this industry must align product portfolios, pricing logic, service systems, and procurement readiness with public health priorities.

At the same time, the Indonesian government has encouraged local industrial participation through Tingkat Komponen Dalam Negeri (TKDN) or Domestic Component Level, which refers to the proportion of domestic goods, services, or production inputs used in a product. The original article reports that 2,718 medical device products had obtained registered TKDN values, while the proportion of domestically distributed medical device licenses had reached approximately 71.3% (Kadin, 2025). In addition, the share of imported products in e-catalogue procurement reportedly declined from approximately 92% before the COVID-19 period to around 52% in 2024, indicating progress in import substitution, while also confirming that import dependence remains substantial, particularly in high-technology segments (Kontan, 2025).

This context creates a strategic tension. On the one hand, medical device firms face expanding demand from hospitals, laboratories, public health programs, and primary-care facilities. On the other hand, they must respond to import dependence, fiscal selectivity, local-content requirements, exchange-rate exposure, procurement reform, and regulatory complexity. Under these conditions, firms cannot rely solely on product availability or conventional selling approaches. They require strategic adaptation through market intelligence, regulatory capability, supply-chain flexibility, financial resilience, local-content readiness, digital procurement literacy, technical service capability, and after-sales differentiation.

Previous studies provide important but fragmented explanations. Pratono, Aluisius Hery; Maharani, (2024) showed that supply-chain resilience in Indonesia's medical device industry is shaped by dynamic capabilities, including adaptive decision-making, partnership restructuring, safety-stock management, and procurement agility. Adji et al, (2025) argued that fiscal policy, import duties, taxation,

and import-substitution strategies influence the resilience and competitiveness of Indonesia's medical device industry. Endika et al., (2025) highlighted the importance of governance transformation, digital monitoring, budget realization, and cross-sector coordination in the pharmaceutical and medical device sectors. (Hooda, 2024) further demonstrated that emerging economies often remain stronger in low-technology medical device segments while continuing to depend on imported advanced equipment.

Despite these contributions, an important research gap remains. Existing studies tend to examine supply-chain resilience, fiscal policy, governance reform, localization, or industrial competitiveness separately. Limited research integrates these issues into a firm-level strategic marketing and management framework that explains how Indonesian medical device firms convert external pressures into adaptive capabilities and sustainable growth. Therefore, this study seeks to address that gap by developing a conceptual framework linking PESTEL-based external pressures, dynamic capabilities, strategic adaptation mechanisms, sustainable competitive advantage, and sustainable growth outcomes.

This study is guided by two research questions:

1. **RQ1:** What external strategic pressures shape firm-level adaptation in Indonesia's medical device industry?
2. **RQ2:** How can medical device firms translate those pressures into adaptive capabilities that support sustainable growth?

This article contributes to strategic marketing and management literature by explaining strategic adaptation not as a generic managerial recommendation, but as a structured capability-building process in a regulated emerging healthcare market.

2. LITERATURE REVIEW AND STATE OF THE ART

This section establishes the theoretical foundation of the article, synthesizes relevant prior studies, identifies the research gap, and formulates conceptual propositions. The discussion is organized around five theoretical streams: strategic market management, dynamic capability theory, market orientation, the resource-based view, and sustainable marketing, with PESTEL analysis used as the external strategic analysis lens.

2.1 Grand Theory: Strategic Market Management

Strategic market management provides the grand theoretical basis for this study because it explains how firms evaluate markets, customers, competitors, environmental changes, internal resources, strategic choices, and implementation processes (Aaker & Moorman, 2018). In the medical device industry, firms do not compete only through product features or price. They compete through regulatory credibility, procurement readiness, clinical reliability, technical service, maintenance capability, and long-term institutional trust. (Porter, 2023) competitive strategy perspective also suggests that firms must identify defensible positions within their industries. In Indonesia's medical device market, many domestic firms may not be able to compete directly with multinational firms in highly advanced technology segments, but they may compete effectively through focused differentiation in areas where local responsiveness, service proximity, procurement compliance, and total cost of ownership are strategically important.

2.2 Middle-Range Theory: Dynamic Capabilities

Dynamic capability theory explains how firms survive and grow in turbulent environments by developing the ability to **sense**, **seize**, and **transform** in response to environmental change (Teece, D. J; Pisano, G; Shuen, 1997). In Indonesia's medical device industry, these capabilities are particularly relevant because firms face simultaneous changes in healthcare financing, exchange rates, procurement systems, local-content rules, global supply chains, and technology demand.

Sensing capability refers to the ability to identify market and policy signals, including public budget priorities, hospital procurement needs, TKDN requirements, exchange-rate movements, and changes in product standards. Seizing capability refers to the ability to capture opportunities through portfolio adjustments, pricing strategies, business-to-business and business-to-government marketing, distributor partnerships, and e-catalogue participation. Transforming capability refers to the ability to reconfigure internal resources such as regulatory affairs, supply chains, local sourcing, service networks, digital systems, and financial-risk management. This study extends the application of dynamic capability theory

by arguing that such capabilities are not only relevant for operational resilience, but are also central to strategic marketing adaptation and sustainable growth.

2.3 Market Orientation and Sustainable Marketing

Market orientation explains how firms create superior performance by understanding customers, competitors, and inter-functional coordination (Kohli & Jaworski, 1990); (Narver & Slater, 1990). In the medical device industry, customer orientation includes understanding the needs of hospital managers, physicians, nurses, biomedical engineers, procurement officers, distributors, regulators, and patients. Competitor orientation requires attention to imported products, local producers, foreign principals, price structures, service standards, and substitute technologies. Inter-functional coordination involves integration across sales, finance, regulatory affairs, inventory, logistics, technical service, and top management.

Sustainable marketing extends this logic by emphasizing long-term value creation rather than short-term promotional activity. In regulated healthcare markets, sustainable marketing involves delivering products and services that are safe, reliable, affordable, maintainable, compliant, and aligned with healthcare-system priorities. (Deng et al., 2025) demonstrated that digital transformation can strengthen sustainable marketing performance through responsive market orientation. This is especially relevant to medical device firms, whose competitiveness increasingly depends on digital procurement readiness, customer relationship management, technical education, complaint handling, and after-sales monitoring.

2.4 Resource-Based View and Sustainable Competitive Advantage

The resource-based view suggests that sustainable competitive advantage arises from resources that are valuable, rare, difficult to imitate, and organizationally embedded (Barney, 1991). In Indonesia’s medical device industry, such resources include regulatory expertise, distribution permits, TKDN documentation, hospital trust, service-engineer capability, spare-part availability, clinical training capacity, digital procurement literacy, and principal relationships. These resources are not easily replicated because they depend on accumulated experience, institutional legitimacy, technical competence, and organizational coordination. Therefore, sustainable growth in this industry cannot be reduced to product availability or price competition; it requires integrated value-delivery systems that combine both tangible and intangible resources.

2.5 PESTEL as the Strategic Environmental Analysis Lens

PESTEL analysis is used to examine the political, economic, social, technological, environmental, and legal factors shaping an industry’s external environment (Yüksel, 2012). In this article, PESTEL is not used merely as a descriptive checklist. Instead, it functions as an analytical bridge between macro-environmental pressures and firm-level capability development.

In the Indonesian medical device industry, the political dimension includes public healthcare policy, industrial policy, procurement governance, and state support for domestic production. The economic dimension includes fiscal selectivity, exchange-rate exposure, import dependence, market growth, and institutional price sensitivity. The social dimension includes patient safety, clinician trust, healthcare demand, hospital utilization, and primary-care needs. The technological dimension includes dependence on imported advanced devices, digital procurement systems, service technology, and local production capability. The environmental dimension includes product lifecycle responsibility, waste management, repairability, and sustainable healthcare operations. The legal dimension includes product registration, distribution permits, safety standards, local-content compliance, and procurement documentation.

2.6 Synthesis of Previous Studies

Table 1. Synthesis of Previous Studies

| Theme | Key Studies | Main Findings | Relevance to This Study |
|---|--|--|---|
| Supply-chain resilience and dynamic capabilities | (Pratono, Aluisius Hery; Maharani, 2024) | Supply-chain resilience depends on adaptive decision-making, partnership restructuring, and procurement agility. | Supports the dynamic capability perspective in medical device adaptation. |

| | | | |
|---|-----------------------|---|---|
| Fiscal policy and import substitution | (Adji et al., 2025) | Fiscal incentives, import duties, and taxation affect domestic medical device resilience. | Supports the role of economic and policy pressures in strategic adaptation. |
| Governance transformation | (Endika et al., 2025) | Governance reform requires digital readiness, budget realization, and cross-sector coordination. | Explains why firms must respond to institutional and regulatory change. |
| Domestic-content policy | (Nova et al., 2025) | TKDN policy influences the development of the medical device industry but requires capability readiness. | Strengthens the legal and industrial-policy dimensions of the framework. |
| Emerging-economy localization challenge | (Hooda, 2024) | Emerging economies remain dependent on imported advanced devices despite local growth in lower-technology segments. | Provides comparative insight into Indonesia's localization challenge. |
| Digital transformation and sustainable marketing | (Deng et al., 2025) | Digital transformation improves sustainable marketing performance through responsive market orientation. | Supports digital readiness and service responsiveness. |

Source: Authors' thematic synthesis

2.7 Research Gap and Conceptual Propositions

The literature reveals that medical device adaptation has often been discussed through fragmented lenses. Supply-chain studies focus on operational resilience, fiscal-policy studies emphasize taxation and import substitution, and governance studies focus on public-sector reform. However, limited research integrates these issues into a coherent strategic framework explaining how Indonesian medical device firms adapt to environmental pressures and convert those pressures into sustainable growth.

Based on this gap, the following conceptual propositions are formulated:

1. **P1:** External strategic pressures, including fiscal selectivity, exchange-rate volatility, import dependence, regulatory change, and TKDN policy, increase the need for strategic adaptation among Indonesian medical device firms.
2. **P2:** Sensing capability enhances a firm's ability to identify market opportunities and institutional risks in Indonesia's regulated healthcare environment.
3. **P3:** Seizing capability enables firms to translate policy and market signals into product portfolio adjustment, e-catalogue participation, value-based pricing, and institutional relationship marketing.
4. **P4:** Transforming capability enables firms to reconfigure regulatory, supply-chain, service, digital, financial, and local-production resources.
5. **P5:** Sustainable growth is achieved when sensing, seizing, and transforming capabilities are institutionalized into sustaining capabilities such as customer trust, policy alignment, after-sales excellence, innovation readiness, and organizational resilience.
6. **P6:** The relationship between strategic adaptation and sustainable growth is strengthened when firms combine market orientation with valuable, rare, inimitable, and organizationally embedded resources such as regulatory expertise, TKDN documentation, institutional trust, and service-engineer capability.
7. **P7:** Environmental and lifecycle-oriented capabilities strengthen sustainable growth when firms integrate repairability, waste reduction, responsible disposal, and maintenance efficiency into their strategic adaptation mechanisms.

2.8 Proposed Conceptual Framework

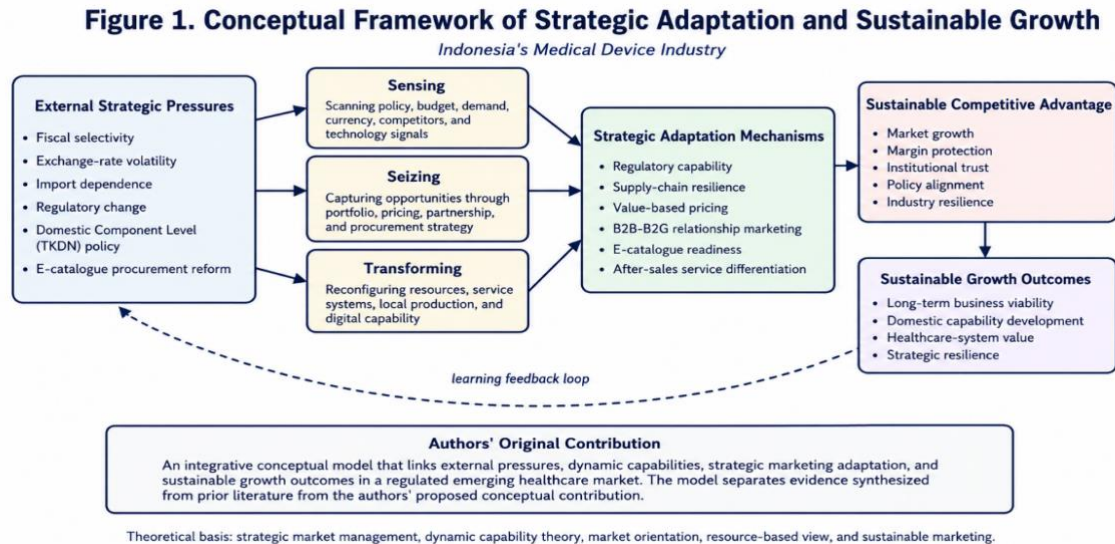


Figure 1. Conceptual Framework of Strategic Adaptation and Sustainable Growth in Indonesia's Medical Device Industry

The proposed framework consists of five connected components:

1. **External industry pressures:** political, economic, social, technological, environmental, and legal pressures identified through PESTEL analysis.
2. **Dynamic capabilities:** sensing, seizing, transforming, and sustaining capabilities.
3. **Strategic adaptation mechanisms:** regulatory intelligence, supply-chain resilience, value-based pricing, business-to-business and business-to-government relationship marketing, e-catalogue readiness, local production capability, technology partnerships, and after-sales service differentiation.
4. **Sustainable competitive advantage:** institutional trust, compliance credibility, margin protection, policy alignment, service reliability, and organizational resilience.
5. **Sustainable growth outcomes:** long-term market continuity, healthcare-system value, domestic capability development, customer retention, and adaptive competitiveness.

The framework can be expressed as follows:

PESTEL-based external pressures → sensing, seizing, transforming, and sustaining capabilities → strategic adaptation mechanisms → sustainable competitive advantage → sustainable growth outcomes.

This framework explains that firms do not achieve sustainable growth simply because the healthcare market expands. Sustainable growth emerges when firms develop the capability to interpret external pressures, capture relevant opportunities, reconfigure internal resources, and institutionalize adaptive routines.

3. RESEARCH METHODS

3.1 Research Design

This study applies a qualitative document analysis design supported by PESTEL-based strategic synthesis. This design is appropriate because the article does not collect primary data through surveys, interviews, experiments, or case studies. Instead, it aims to interpret and synthesize academic literature, policy documents, institutional reports, and selected industry sources to develop a conceptual explanation of strategic adaptation and sustainable growth in Indonesia's medical device industry. Document analysis is suitable for examining policy-driven and institutionally shaped business phenomena because it enables researchers to interpret formal documents, scholarly studies, and contextual evidence systematically

(Bowen, 2009). Conceptual research is also appropriate when the objective is to integrate fragmented literature and develop a theoretically grounded framework rather than to statistically test causal relationships (Jaakkola, 2020); (Snyder, 2019).

The research paradigm is interpretive-conceptual. This paradigm is used because the study seeks to understand how external industry pressures are interpreted, categorized, and translated into firm-level strategic responses. The unit of analysis is document-based evidence related to medical device industry dynamics, strategic adaptation, dynamic capabilities, market orientation, local-content policy, regulatory requirements, and sustainable growth.

3.2 Research Context

The object of analysis is Indonesia’s medical device industry, particularly firm-level adaptation under fiscal, regulatory, procurement, technological, and macroeconomic pressures. Indonesia was selected because its medical device industry is strategically significant but still underrepresented in management and strategic marketing literature. The sector is characterized by a combination of healthcare demand expansion, import dependence, domestic-content policy, public procurement reform, and institutional buyer dominance. These conditions make Indonesia a relevant emerging-market context for conceptualizing strategic adaptation and sustainable growth.

3.3 Data Sources and Document Selection

Data sources consist of peer-reviewed journal articles, policy documents, institutional reports, and selected industry publications. Peer-reviewed studies are prioritized as the main scholarly evidence, while policy and institutional documents are used to contextualize Indonesia’s medical device governance, healthcare financing, procurement reform, TKDN policy, and industrial development. News and business media sources are not treated as primary scholarly evidence; they are used only when they report official statements, recent policy developments, or market conditions that are not yet available in academic publications.

Documents were selected purposively based on four criteria. First, they had to be relevant to strategic adaptation, medical device industry development, dynamic capabilities, healthcare procurement, supply-chain resilience, local-content policy, fiscal pressure, digital transformation, regulatory capability, or sustainable growth. Second, they had to relate directly to Indonesia or to comparable emerging-market contexts. Third, recent publications from 2021 to 2025 were prioritized, while seminal theories were retained where necessary to establish the theoretical foundation. Fourth, the sources had to demonstrate credibility through peer-reviewed publication, institutional authorship, policy relevance, or clear methodological basis. Documents were excluded when they were promotional, unrelated to the core constructs, methodologically unclear, unsupported by identifiable institutional or scholarly authority, or repetitive without contributing new analytical insight.

Table 2. Document Selection Profile

| Source Category | Sources Mapped | Sources Analyzed | Main Function in the Study | Examples of Sources Used |
|--------------------------------|----------------|------------------|--|--|
| Peer-reviewed journal articles | 38 | 22 | To support theoretical foundation, prior empirical findings, methodological justification, supply-chain resilience, digital transformation, sustainability, and strategic adaptation analysis. | (Barney, 1991); Kohli and Jaworski (1990); (Narver & Slater, 1990); (Teece, D. J; Pisano, G; Shuen, 1997); Teece (2018); (Pratono, Aluisius Hery; Maharani, 2024); Ivanov and (Ivanov, Dmitry; Dolgui, 2020); (Spieske et al., 2020)); (Kraus, Sascha & Schiavone, Francesco & Pluzhnikova, Anna & Invernizzi, 2021); (Montesinos et al., 2024). |
| Scholarly books | 4 | 2 | To establish foundational theories in strategic market management and competitive strategy. | (Aaker & Moorman, 2018); (Porter, 2023). |

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|---|-----------|-----------|---|--|
| Methodological references | 6 | 4 | To justify qualitative document analysis, thematic synthesis, conceptual article design, and literature review methodology. | (Bowen, 2009); (Braun & Clarke, 2006); (Jaakkola, 2020); (Snyder, 2019). |
| Institutional and policy sources | 5 | 2 | To contextualize Indonesia's healthcare policy, medical device governance, TKDN policy, and import dependence. | (U.S. International Trade Administration, 2025); (Kadin, 2025). |
| Industry and market reports | 4 | 1 | To provide market size, growth projection, and industry outlook data. | (Nexdigm, 2025). |
| News and business media sources | 6 | 2 | To support recent contextual information not yet widely available in peer-reviewed literature, particularly health budget allocation and e-catalogue import dynamics. | (Antara, 2025); (Kontan, 2025). |
| Total | 63 | 33 | To support PESTEL coding, thematic synthesis, contextual interpretation, and framework development. | — |

Source: Authors' document mapping and selection.

The analysed sources were not treated equally in the synthesis. Peer-reviewed journal articles and scholarly books were used as the primary basis for theory development and conceptual argumentation. Institutional and policy sources were used to clarify the regulatory and policy context of Indonesia's medical device industry. Industry reports and media sources were used only to support contextual statistics, such as market size, public health budget allocation, import dependence, and e-catalogue procurement trends. This hierarchy of evidence was applied to ensure that the conceptual framework was grounded primarily in academic literature while remaining sensitive to current industry realities.

3.4 Analytical Technique

The primary analytical technique is PESTEL analysis. In this study, PESTEL refers to political, economic, social, technological, environmental, and legal analysis. The political dimension examines public health policy, industrial policy, procurement reform, and government support for domestic medical device production. The economic dimension examines fiscal selectivity, exchange-rate exposure, import dependence, market growth, and price sensitivity. The social dimension examines healthcare demand, hospital utilization, patient safety expectations, clinician trust, and primary-care needs. The technological dimension examines local production capability, high-technology dependence, digital procurement, e-catalogue readiness, and after-sales service technology. The environmental dimension examines product lifecycle responsibility, waste management, reparability, maintenance efficiency, green procurement, and sustainable healthcare operations. The legal dimension examines product registration, distribution permits, safety standards, local-content compliance, procurement requirements, and regulatory documentation.

The analysis was conducted in four stages. First, document mapping was used to identify relevant academic, institutional, policy, and industry sources. Second, PESTEL coding was conducted by classifying extracted information into political, economic, social, technological, environmental, and legal dimensions. Third, thematic synthesis was used to identify cross-cutting patterns among the PESTEL dimensions, especially the interaction between fiscal pressure, import dependence, procurement reform, local-content policy, regulatory capability, and firm-level capability development. Fourth, theoretical integration was

conducted by linking the PESTEL findings with strategic market management, dynamic capability theory, market orientation, the resource-based view, and sustainable marketing. This final stage produced the proposed conceptual framework connecting external industry pressures with sensing, seizing, transforming, and sustaining capabilities.

3.5 Trustworthiness and Analytical Rigor

Trustworthiness was strengthened through source triangulation and theory triangulation. Source triangulation was conducted by comparing peer-reviewed studies with policy documents and institutional reports. Theory triangulation was conducted by interpreting the findings through strategic market management, dynamic capability theory, market orientation, the resource-based view, and sustainable marketing. Thematic analysis principles were used to organize extracted evidence into coherent analytical categories ((Braun & Clarke, 2006)).

This study does not claim to produce statistically generalizable findings. It does not use survey data, interviews, firm-level financial data, experiments, or econometric modelling. Therefore, the analytical outputs should be interpreted as conceptual and strategic synthesis rather than empirical validation. The value of the study lies in theory integration, structured environmental analysis, and the development of a framework that can guide future empirical testing.

4. RESULTS AND DISCUSSION

4.1 PESTEL-Based Analytical Findings

The PESTEL analysis shows that Indonesia’s medical device industry is shaped by six interrelated external forces: political, economic, social, technological, environmental, and legal. These forces do not operate independently. Instead, they interact to create a strategic environment in which firms must adapt their market positioning, procurement readiness, supply-chain structure, regulatory capability, and long-term growth strategy.

Table 3. PESTEL-Based Analytical Framework for Indonesia’s Medical Device Industry

| PESTEL Dimension | Key Analytical Finding | Strategic Pressure or Opportunity | Firm-Level Strategic Implication |
|----------------------|---|--|--|
| Political | Healthcare financing, public procurement, and local industrial policy shape medical device demand. | Public-sector priorities and procurement rules influence market access. | Firms must develop government-market intelligence, institutional relationship capability, and procurement readiness. |
| Economic | Market growth is accompanied by fiscal selectivity, exchange-rate exposure, and import dependence. | Growth opportunity coexists with cost pressure and margin risk. | Firms need value-based pricing, currency-risk management, local sourcing, and supplier diversification. |
| Social | Demand is driven by hospital modernization, primary-care needs, patient safety, and clinician trust. | Buyers require reliability, training, safety, and service continuity. | Firms must strengthen clinical education, after-sales service, user training, and trust-based relationship marketing. |
| Technological | Advanced medical devices remain import-dependent, while digital procurement and service systems are increasingly important. | Technology gaps create vulnerability but also opportunities for digital adaptation. | Firms need e-catalogue readiness, technical service capability, digital customer relationship management, and technology partnerships. |
| Environmental | Healthcare systems increasingly require responsible product lifecycle management and sustainable operations. | Waste, energy use, packaging, and equipment lifecycle may become procurement considerations. | Firms should adopt lifecycle-based service, maintenance efficiency, spare-part planning, and environmentally responsible disposal practices. |

| | | | |
|--------------|--|--|--|
| Legal | Medical devices are governed by product registration, standards, permits, local-content rules, and compliance. | Regulatory compliance becomes a condition for market access. | Firms must build intelligence, documentation capability, TKDN readiness, and compliance-based differentiation. |
|--------------|--|--|--|

Source: Authors' PESTEL-based strategic synthesis.

4.2 Discussion of Political and Legal Findings: Procurement, Regulation, and Institutional Market Access

The political and legal findings show that Indonesia's medical device industry is strongly shaped by public procurement, healthcare financing, industrial policy, product registration, safety standards, TKDN requirements, and procurement compliance. This finding is consistent with strategic market management theory, which argues that firms must align their market strategies with external environmental conditions and institutional constraints (Aaker & Moorman, 2018). It is also consistent with (Porter, 2023) view that competitive positioning depends on the structure of the industry and the rules governing buyer-supplier interaction.

Previous studies support this interpretation. Pratono and Maharani (2024) showed that Indonesia's medical device supply chain involves multiple stakeholders, including manufacturers, channel partners, hospital management, and end users, and that resilience is shaped by procurement agility and dynamic capability. Spieske et al., (2020) found that healthcare supply-chain resilience during the COVID-19 crisis depends on procurement strategies that combine buffering and bridging approaches across manufacturers and hospital groups. Endika et al. (2025) also emphasized that governance transformation in Indonesia's pharmaceutical and medical device sectors requires digital monitoring, budget realization, and cross-sector coordination.

In the Indonesian field context, this means that market access is not determined solely by product demand. Firms must understand procurement cycles, government priorities, e-catalogue rules, distribution permits, and TKDN documentation. The real phenomenon of public hospitals contributing a significant share of device revenues and the role of BPJS Kesehatan in financing healthcare demand demonstrate that the state functions not only as regulator but also as market shaper. Therefore, political and legal adaptation requires firms to develop business-to-government capabilities, regulatory intelligence, and compliance-based differentiation.

Critically, this finding implies that firms with superior regulatory and procurement capabilities may outperform competitors even when their products are not technologically superior. In regulated healthcare markets, legitimacy, documentation, institutional trust, and compliance credibility can become strategic assets. From the resource-based view, these capabilities are valuable and difficult to imitate because they are built through accumulated institutional experience, legal knowledge, and stakeholder relationships (Barney, 1991). Therefore, regulatory capability should not be treated as a back-office administrative function, but as a central component of competitive advantage.

4.3 Discussion of Economic Findings: Import Dependence, Fiscal Selectivity, and Supply-Chain Resilience

The economic findings indicate that Indonesia's medical device market is expanding, but this growth is accompanied by import dependence, exchange-rate exposure, fiscal selectivity, and margin pressure. This finding is consistent with dynamic capability theory because firms operating under volatile economic conditions must continuously sense cost risks, seize procurement opportunities, and transform supply-chain configurations (Teece, D. J; Pisano, G; Shuen, 1997); Teece, 2018).

International studies on supply-chain resilience strengthen this argument. (Ivanov, Dmitry; Dolgui, 2020) emphasized that modern supply chains should be understood as intertwined networks whose viability depends on resilience, survivability, and adaptive redesign. Abdolazimi, O et al., (2023) demonstrated that sustainable and resilient healthcare distribution systems must balance cost, environmental impact, lead time,

and risk exposure. Modgil et al. (2022) showed that digital and artificial intelligence-enabled capabilities can strengthen supply-chain resilience by improving visibility, risk management, sourcing, and distribution. Pratono and Maharani (2024) similarly demonstrated that Indonesian medical device supply chains require agility, partnership restructuring, safety-stock management, and adaptive procurement practices.

In the Indonesian context, the projected trade deficit and continued dependence on imported high-technology devices show that firms remain exposed to foreign-currency volatility and global supply disruptions. Even when domestic production increases, the localization of advanced equipment remains difficult due to technology gaps, component limitations, and quality-assurance requirements. Fiscal selectivity also means that public and institutional buyers increasingly evaluate products not only by purchase price, but by total cost of ownership, maintenance cost, spare-part availability, warranty reliability, and service continuity.

The critical implication is that sustainable growth requires a shift from price competition to value-based competitiveness. Firms need to communicate product value through lifecycle cost, service reliability, training, technical support, and risk reduction. Importers and distributors must build supplier diversification, currency-risk management, and spare-part continuity. Local manufacturers must develop sourcing networks and quality systems. Therefore, economic pressure does not simply threaten firms; it also pushes firms to build more resilient and differentiated business models.

4.4 Discussion of Social Findings: Patient Safety, Clinician Trust, and Service Reliability

The social findings show that healthcare demand, hospital modernization, patient safety, clinician trust, and primary-care needs influence medical device adoption. This finding is aligned with market orientation theory, which emphasizes customer orientation, competitor orientation, and inter-functional coordination (Kohli & Jaworski, 1990; Narver & Slater, 1990). In the medical device industry, customers are not limited to purchasing departments. They include hospital managers, physicians, nurses, laboratory personnel, biomedical engineers, procurement officers, distributors, regulators, and patients.

Previous studies support this broader stakeholder view. (Kraus, Sascha & Schiavone, Francesco & Pluzhnikova, Anna & Invernizzi, 2021) showed that digital transformation in healthcare involves multiple stakeholders and requires the implementation of digital technologies for management, operational, and patient-related purposes. Spieske et al., (2020) also demonstrated that supply availability in healthcare depends on coordination among suppliers, manufacturers, and hospital procurement actors. (Deng et al., 2025) further found that digital transformation strengthens sustainable marketing performance through responsive market orientation, suggesting that firms need to respond continuously to evolving customer and institutional needs.

In the Indonesian field context, medical device firms operate in an environment where product reliability, user training, calibration, maintenance, and after-sales service directly affect clinical performance and patient safety. A device that is available but difficult to operate, repair, calibrate, or maintain may fail to generate institutional trust. Public and private hospitals are likely to prefer suppliers that can provide training, spare parts, technical support, and rapid service response.

Critically, this means that medical device competitiveness is relational and service-based, not merely product-based. Firms that focus only on selling equipment may achieve short-term revenue but fail to build long-term customer retention. In contrast, firms that develop service engineers, clinical education programs, complaint-handling systems, and responsive after-sales mechanisms can create trust-based differentiation. Thus, social pressure strengthens the argument that sustainable growth depends on market orientation and service capability.

4.5 Discussion of Technological Findings: Digital Procurement, Technology Dependence, and Capability Transformation

The technological findings indicate that Indonesia's medical device industry faces a dual challenge. On the one hand, advanced devices remain difficult to localize. On the other hand, digital procurement, e-catalogue readiness, customer relationship management, remote service support, and data-based after-sales systems are becoming increasingly important. This finding is consistent with dynamic capability theory

because technology-related turbulence requires firms to transform internal routines and develop new digital capabilities (Teece et al., 1997; Teece, 2018).

International studies provide strong support for this interpretation. (Kraus, Sascha & Schiavone, Francesco & Pluzhnikova, Anna & Invernizzi, 2021) demonstrated that digital transformation in healthcare is increasingly important for management and business purposes across multiple stakeholders. Modgil et al. (2022) showed that artificial intelligence-enabled supply-chain capabilities improve resilience by strengthening visibility, risk identification, sourcing, and distribution capabilities. (Deng et al., 2025) found that digital transformation supports sustainable marketing performance when combined with responsive market orientation. These studies collectively suggest that digital capability is not only a technological tool, but also a strategic enabler of responsiveness, coordination, and resilience.

In Indonesia, the expansion of e-catalogue procurement means that firms must manage digital documentation, product listing, pricing transparency, and procurement compliance. Firms also need digital customer relationship management systems to monitor complaints, maintenance schedules, spare-part needs, and service quality. For local producers, technology partnerships are important because advanced medical device production often requires technology transfer, technical standards, and specialized components.

Critically, the technological dimension shows that localization should not be interpreted narrowly as physical production. Localization also includes knowledge capability, service capability, digital capability, regulatory capability, and supplier development. Firms may not immediately produce advanced devices domestically, but they can still build competitive advantage through digital service systems, local maintenance networks, product adaptation, and technology partnerships. Therefore, technological adaptation is both a manufacturing issue and a strategic capability issue.

4.6 Discussion of Environmental Findings: Lifecycle Responsibility and Sustainable Healthcare Operations

The environmental findings show that medical device firms increasingly need to address lifecycle responsibility, waste management, repairability, maintenance efficiency, packaging, and responsible disposal. This finding is aligned with sustainable marketing, which emphasizes long-term value creation for customers, firms, society, and the environment. It also extends the sustainable growth concept beyond financial performance.

Recent literature supports the growing importance of this issue. Montesinos et al., (2024) showed that sustainability concerns exist across the medical device lifecycle, including design, manufacturing, use, and end-of-life management. Their review emphasizes that medical devices can generate environmental impacts through energy use, material consumption, single-use products, electronic waste, and disposal practices. Abdolazimi, O et al., (2023) also showed that healthcare distribution systems must balance cost, risk, lead time, and environmental impact, indicating that resilience and sustainability should be integrated rather than treated separately.

In Indonesia, environmental criteria may not yet dominate medical device procurement, but the issue is becoming increasingly relevant as healthcare systems seek more sustainable operations. Hospitals generate medical waste and often face maintenance and disposal challenges. Devices with short lifecycles, limited spare-part availability, or poor repairability can increase waste and operational inefficiency. Therefore, environmental responsibility may gradually become part of institutional purchasing criteria, particularly in large hospitals, government programs, and international-standard healthcare facilities.

Critically, environmental sustainability should not be treated as a peripheral issue. For medical device firms, lifecycle responsibility can become a source of differentiation. Firms that offer repairable devices, spare-part continuity, maintenance-efficient products, responsible disposal programs, and lifecycle-based service contracts may build stronger long-term legitimacy. This suggests that sustainable growth requires firms to integrate environmental considerations into product strategy, service design, and procurement communication.

4.7 Discussion of Strategic Integration: From PESTEL Pressures to Dynamic Capabilities

The integration of PESTEL analysis with dynamic capability theory provides the central theoretical contribution of this study. PESTEL explains the external structure of industry pressures, while dynamic

capability theory explains the internal process through which firms respond. This integration is consistent with Teece’s (2018) argument that dynamic capabilities support business model adaptation and long-term strategy under environmental change.

The field context of Indonesia’s medical device industry demonstrates why this integration is necessary. Political and legal pressures require regulatory intelligence and procurement readiness. Economic pressures require value-based pricing, financial resilience, and supply-chain diversification. Social pressures require service reliability and trust-building. Technological pressures require digital readiness, e-catalogue capability, and selective localization. Environmental pressures require lifecycle responsibility and sustainable service systems.

The critical meaning of this synthesis is that strategic adaptation cannot be reduced to a single functional improvement. Firms cannot respond to import dependence only through supplier diversification, because import dependence is also linked to technology gaps, currency risk, procurement rules, and local-content policy. Similarly, firms cannot respond to TKDN policy only through documentation, because effective localization also requires supplier development, quality assurance, technology transfer, and production capability. Therefore, the PESTEL–dynamic capability framework shows that sustainable growth emerges from systemic capability alignment rather than isolated tactical responses.

4.8 PESTEL–Dynamic Capability Translation Matrix

Table 4. PESTEL–Dynamic Capability Translation Matrix

| PESTEL Pressure | Sensing Capability | Seizing Capability | Transforming Capability | Sustaining Capability |
|---|---|---|---|---|
| Political: healthcare policy and public procurement | Monitor public health priorities, procurement rules, and budget direction. | Enter relevant procurement channels and build institutional relationships. | Develop business-to-government processes and policy-aligned product portfolios. | Maintain legitimacy, public-sector trust, and long-term procurement access. |
| Economic: fiscal selectivity and exchange-rate exposure | Track exchange-rate movement, import costs, and buyer price sensitivity. | Apply value-based pricing and total cost-of-ownership communication. | Diversify suppliers, localize sourcing, and strengthen financial-risk management. | Protect margins and sustain affordability under cost pressure. |
| Social: patient safety and clinician trust | Identify user needs, clinical expectations, and service pain points. | Provide training, clinical education, and responsive after-sales support. | Build service-engineer teams and customer relationship systems. | Strengthen institutional trust and user loyalty. |
| Technological: import dependence and digital procurement | Monitor technology trends, e-catalogue changes, and local production feasibility. | Form technology partnerships and prioritize feasible localization segments. | Build digital procurement capability, technical service systems, and product adaptation capacity. | Sustain innovation readiness and service reliability. |
| Environmental: lifecycle responsibility | Identify sustainability expectations in healthcare operations. | Offer maintenance-efficient, repairable, and lifecycle-conscious solutions. | Develop spare-part systems, repair protocols, and responsible disposal practices. | Support sustainable healthcare operations and long-term reputation. |
| Legal: regulation and compliance | Monitor product registration rules, safety standards, and TKDN requirements. | Use compliance readiness as a market-access strategy. | Strengthen regulatory affairs, documentation systems, and audit readiness. | Maintain compliance credibility and reduce institutional risk. |

Source: Authors’ conceptual synthesis.

This matrix represents the article's core conceptual contribution. It shows that PESTEL is not merely a descriptive tool for listing external factors. Instead, PESTEL becomes an analytical bridge connecting external industry pressures with dynamic capabilities and sustainable competitive advantage. The framework explains that firms must first sense PESTEL-based pressures, then seize opportunities, transform internal resources, and sustain competitive advantage through institutional trust, service reliability, policy alignment, compliance credibility, and operational resilience.

4.9 Theoretical Implications

Theoretically, this study contributes to strategic marketing and management literature in four ways. First, it extends PESTEL analysis from a descriptive macro-environmental tool into a theory-linked strategic synthesis framework. Second, it extends dynamic capability theory by showing how sensing, seizing, transforming, and sustaining capabilities can be structured through PESTEL-based external analysis. Third, it integrates strategic market management, market orientation, the resource-based view, sustainable marketing, and healthcare supply-chain resilience into a single explanation of sustainable growth in a regulated emerging healthcare market. Fourth, it adds an environmental lifecycle dimension to the discussion of medical device competitiveness, thereby broadening the meaning of sustainable growth beyond market and financial performance.

4.10 Practical Implications

For medical device firms, the findings suggest that strategic adaptation should begin with systematic PESTEL scanning. Firms should monitor public health policy, procurement reform, fiscal allocation, exchange-rate movement, hospital demand, digital procurement systems, environmental expectations, and regulatory requirements. This scanning should be translated into product portfolio decisions, pricing strategy, local-content planning, service-network development, partnership formation, and regulatory documentation.

For local manufacturers, the framework implies that TKDN compliance should not be treated merely as an administrative requirement. It should be integrated with quality assurance, supplier development, production capability, service readiness, and procurement strategy. For importers and distributors, the framework implies that competitiveness depends not only on product availability but also on after-sales reliability, spare-part continuity, pricing flexibility, training, and compliance documentation.

For policymakers, the findings suggest that domestic medical device competitiveness cannot be achieved through local-content requirements alone. TKDN policy should be supported by supplier development, technology transfer, research and development incentives, quality assurance systems, skilled human resources, and predictable procurement rules. Without capability-building support, local-content policy may increase compliance pressure without producing sustainable industrial competitiveness.

4.11 Boundary Conditions

The proposed framework is most relevant for regulated healthcare markets where demand is strongly influenced by public procurement, reimbursement systems, institutional buyers, import dependence, and policy-driven localization. The framework may be less applicable to purely consumer-driven medical device markets, highly liberalized healthcare systems, or industries where procurement decisions are not strongly shaped by state policy and institutional financing. Therefore, future research should examine whether the framework remains valid across different regulatory systems, firm sizes, product categories, and ownership structures.

4.12 Limitations and Future Research

This study is limited by its qualitative document-based design. It does not use survey data, interviews, firm-level financial data, case studies, or statistical modelling. Therefore, the proposed PESTEL–dynamic capability framework should be interpreted as a conceptual contribution rather than an empirically validated causal model. Future studies should test the framework through expert interviews, surveys, multiple-case studies, or structural equation modelling involving medical device manufacturers, distributors, importers, hospital procurement officers, biomedical engineers, policymakers, and industry associations. Future research may also compare different product categories, such as consumables, diagnostic devices, laboratory equipment, and high-technology devices, to examine whether PESTEL pressures affect each segment differently.

5. CONCLUSION

The first research question is answered by identifying political, economic, social, technological, environmental, and legal pressures as the main external drivers of firm-level adaptation. The second is answered by explaining how these pressures are translated into sensing, seizing, transforming, and sustaining capabilities. This study concludes that Indonesia's medical device industry is a strategic context where growth opportunities coexist with fiscal selectivity, exchange-rate exposure, import dependence, regulatory change, local-content policy, and sustainability expectations. Thus, sustainable growth requires dynamic capabilities, market orientation, resource integration, regulatory capability, and sustainable marketing.

The proposed PESTEL–dynamic capability framework explains that sensing helps firms identify fiscal, regulatory, procurement, technological, environmental, and market signals. Seizing enables firms to capture opportunities through portfolio adjustment, e-catalogue participation, B2B–B2G relationship marketing, value-based pricing, and TKDN alignment. Transforming enables firms to reconfigure regulatory, supply-chain, digital, service, financial, and local-production resources, while sustaining converts adaptation into trust, compliance credibility, service reliability, resilience, and long-term growth. Theoretically, this study integrates PESTEL analysis with dynamic capability theory; practically, it guides firms to align strategy with procurement reform, local-content policy, digital readiness, regulatory intelligence, and healthcare-system sustainability.

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