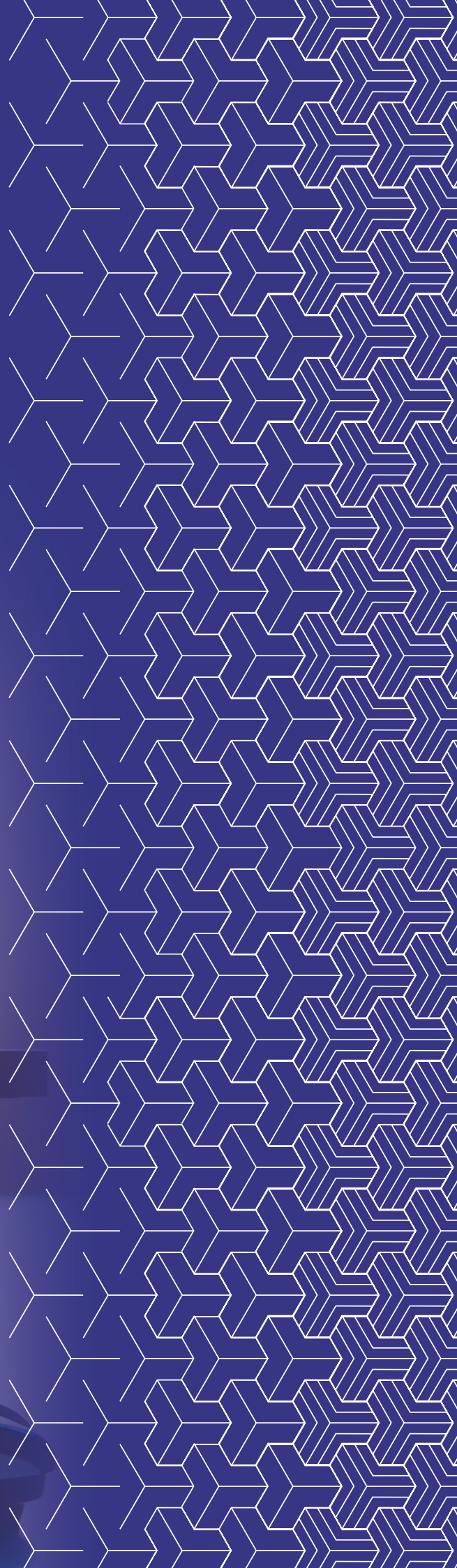


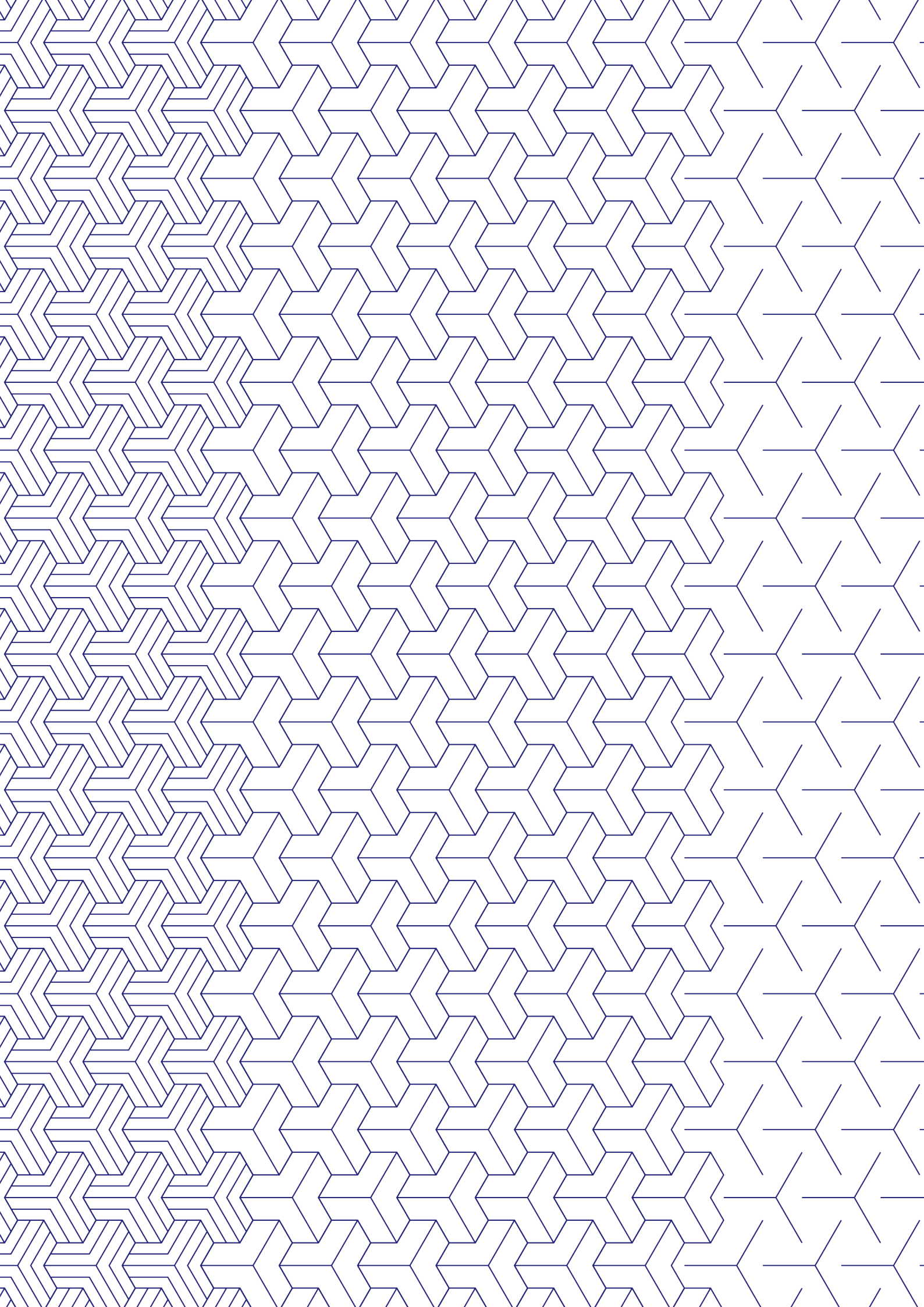


MINISTRY OF INVESTMENT,
TRADE AND INDUSTRY

NEW INDUSTRIAL
MASTER PLAN 2030

MEDICAL DEVICES INDUSTRY





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PREFACE

Malaysia's strength in the manufacturing sector has been significantly driven by the implementation of robust and forward-thinking Industrial Master Plans, first launched in 1986.

The success of the IMP3 (2006-2020) was anchored on innovation, research and development (R&D) and human capital development to drive high value-added industries to transform Malaysia into a knowledge-based economy.

The journey towards formulating the NIMP 2030 is underscored by the need to build a robust industrial sector as an important prerequisite to achieve socioeconomic prosperity. Three previous iterations of the Industrial Master Plans have driven industrial development in Malaysia, with the Government adopting industrial development strategies relevant to the period to transform the economy. Malaysia flourished from a low-productivity agrarian-based economy and is heading towards achieving developed nation status, underpinned by robust manufacturing and services sectors. The strategy has successfully raised the living standards of the Rakyat and propelled remarkable growth in Gross National Income (GNI) per capita, increasing 34 times between 1967 to 2019, making Malaysia one of the fastest growing economies in modern history.

Industrial policies have since become more diverse and complex, incorporating new imperatives including the integration into the global value chain (GVC), development of indigenous capabilities in a knowledge economy, evolution of environmental, social and governance (ESG) criteria and disruptions from the new industrial revolution. The question is not about the necessity of such policies, but rather what new policies are required and how to proceed.

Given the current challenging environment, benchmarking and learning from other country's experiences are no longer sufficient. Malaysia needs to embark on its own path into uncharted territory, to steer the nation into the challenging future. The combined impact of the new imperatives and the recent pandemic has compelled the Government to rethink Malaysia's industrial strategy.

With the NIMP 2030, Malaysia intends to transform the industry into greater heights, capitalising on emerging global trends, supply chain disruptions, current geopolitical landscape, digitalisation and ESG considerations. These trends are moving at an unprecedented pace and Malaysia has to act fast.

Therefore, the NIMP 2030 is designed to achieve the aspirations in a span of seven years and takes on a Mission-based approach for industrial development. This approach unites Malaysia by encouraging collaboration between the Government and the private sector to rally the industries.

Purpose of the NIMP 2030

The NIMP 2030 sets forth Malaysia's future direction in industrial transformation. It provides a national integrated plan for resilient industrial development until 2030 – setting the fundamentals for future policy development and enabling the industry at all levels. It articulates Malaysia's position and participation in the global economic environment.

The NIMP 2030 serves to:

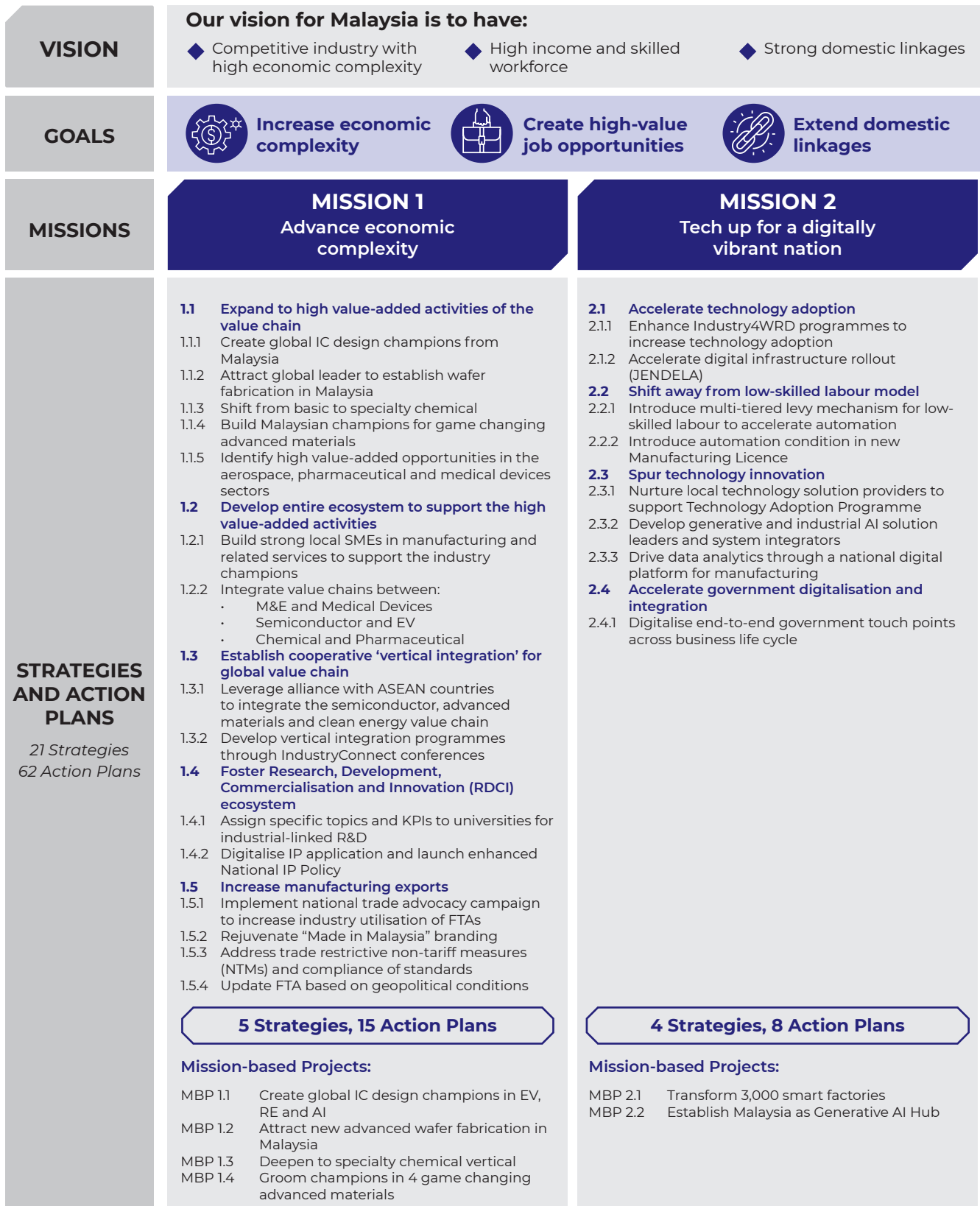
- Provide national strategic direction to lead the industrial development policies;
- Be a conversation piece for investors and other economies on Malaysia's position and direction; and
- Feature the role of the Malaysian Government in shaping the economy.

INTRODUCTION

New Industrial Master Plan 2030

The Missions and Enablers identified will be executed through 21 Strategies and 62 Actions Plans to unlock the needed enabling ecosystems. Several catalytic Mission-based

Projects (MBPs) have been identified to catapult the mission-based implementation. The NIMP 2030 strategic framework is illustrated below:



◆ New and existing industry clusters

◆ Balanced and inclusive participation

◆ Sustainable development



Develop new & existing clusters



Improve inclusivity



Enhance ESG practices

MISSION 3 Push for Net Zero

MISSION 4 Safeguard economic security and inclusivity

ENABLERS

- 3.1 Accelerate transition towards sustainable practices**
 - 3.1.1 Develop sectoral decarbonisation pathways to guide transition
 - 3.1.2 Decarbonise “hard-to-abate” sectors
 - 3.1.3 Introduce carbon policy, accounting and tax
 - 3.1.4 Launch iESG framework and transition programmes
- 3.2 Transition to renewable and clean energy**
 - 3.2.1 Enhance adoption scheme for energy efficiency or renewable energy
 - 3.2.2 Accelerate availability and accessibility of renewable energy source for the industry
- 3.3 Catalyse new green growth areas**
 - 3.3.1 Catalyse EV as a key growth driver
 - 3.3.2 Grow carbon capture, utilisation and storage (CCUS) as a new sector
 - 3.3.3 Develop circular economy framework for the industry
- 3.4 Shift towards green infrastructure**
 - 3.4.1 Accelerate transformation of industrial estates into eco-industrial parks

- 4.1 Develop resilient supply chain**
 - 4.1.1 Identify specific supply chain resilience strategies for critical sectors
 - 4.1.2 Establish supply chain cooperation and collaboration through G2G and G2B programme
 - 4.1.3 Introduce National Mineral Policy for downstream processing of critical minerals
- 4.2 Foster climate resilient development**
 - 4.2.1 Develop sectoral adaptation pathways
 - 4.2.2 Foster an adaptation industry to provide adaptation products and services (including exports)
 - 4.2.3 Instil climate resilience measures for critical economic infrastructure
- 4.3 Strengthen industrial clusters for regional development**
 - 4.3.1 Expand clusters for spillover regional impact
 - 4.3.2 Align industrial development plan between Federal and States
- 4.4 Empower Bumiputera participation and create inclusive workforce**
 - 4.4.1 Uplift capabilities of *Bumiputera* companies in manufacturing via *Tindakan Pembangunan Bumiputera 2030*
 - 4.4.2 Develop programme to increase women participation in high-skilled manufacturing employment

- E.1 Mobilise financing ecosystem**
 - E.1.1 Introduce NIMP Industrial Development Fund and NIMP Strategic Co-Investment Fund
 - E.1.2 Boost financing for digitalisation and decarbonisation transition
 - E.1.3 Establish green *sukuk* to facilitate transition
 - E.1.4 Establish supply chain financing for SMEs
 - E.1.5 Increase utilisation of the capital market
 - E.1.6 Expand the imSME platform to show all available funding options including government funding and capital market
 - E.1.7 Review government funding for consolidation
- E.2 Foster talent development and attraction**
 - E.2.1 Leverage mynext and MYFutureJobs for strategic workforce planning to address long-term demand-supply requirement
 - E.2.2 Introduce progressive wage system policy
 - E.2.3 Improve policy to enable fast and hassle-free access to high-skilled foreign talents
 - E.2.4 Expand TVET programmes for high-skilled jobs in critical sectors
 - E.2.5 Raise profile of high-tech manufacturing career to attract interest in STEM subjects
- E.3 Establish best-in-class investor journey for ease of doing business**
 - E.3.1 Establish a unified investment strategy and align investment evaluation to new parameters under NIA
 - E.3.2 Harmonise and streamline functions and KPIs across IPA landscape
 - E.3.3 Review and design competitive, agile and relevant incentives
 - E.3.4 Improve One-Stop Portal for seamless investor experience
- E.4 Introduce whole-of-nation governance framework**
 - E.4.1 Establish public-private collaborative councils
 - E.4.2 Set up NIMP 2030 Delivery Management Unit
 - E.4.3 Develop NIMP 2030 dashboard system

4 Strategies, 10 Action Plans

Mission-based Projects:

- MBP 3.1 Create decarbonisation pathway role models
- MBP 3.2 Launch locally-manufactured EV
- MBP 3.3 Deploy large-scale CCUS solutions

4 Strategies, 10 Action Plans

4 Strategies, 19 Action Plans

NIMP 2030 SECTORAL PLAN

There are individual enclosures of 21 sectors included as a supplementary reference to the main NIMP 2030 document.

They provide a view of the respective sectoral perspective in the context of the main NIMP 2030 document, and were developed with reference to individual sectoral roadmaps, where applicable.

The 21 sectors are:

Category	Industry
Priority Sectors	<ol style="list-style-type: none"> 1. Aerospace 2. Chemical 3. Electrical and Electronics (E&E) 4. Pharmaceutical 5. Medical Devices
Sectors	<ol style="list-style-type: none"> 6. Digital and Information and Communication Technology (ICT) 7. Automotive 8. Food Processing 9. Global Services and Professional Services 10. <i>Halal</i> 11. Machinery and Equipment (M&E) 12. Manufacturing-Related Services (MRS) 13. Metal 14. Mineral 15. Palm Oil-based Products 16. Petroleum Products and Petrochemicals 17. Rail 18. Rubber-based Products 19. Shipbuilding and Ship Repair (SBSR) 20. Textile, Apparel and Footwear 21. Wood, Paper and Furniture

This document is the [NIMP 2030 Sectoral Plan – Medical Devices Industry](#).

OVERVIEW OF THE DOCUMENT

This NIMP 2030 Sectoral Plan – Medical Devices Industry (Document) provides insights into the sector and its prospects during the NIMP 2030 period.

This Document offers a comprehensive understanding of the industry's direction during the NIMP 2030 period based on its historical performance, opportunities and strategies to overcome existing challenges and achieve its targets.

The Document is presented in five sections:

1. Background

- This section sets the foundation to help readers understand the industry.
- It delves into the industry's focus area, encompassing its sub-sectors, for a comprehension of the industry's breadth.¹
- Readers will find details about the industry's value chain and its key players, including the relevant industry associations, in this section.
- The section lists the policies that are related to the industry.

2. Performance

- This section reports the industry's performance during specific periods.
- There are two notable periods for the review of the industry's historical performance:
 - the IMP3 period (2006 to 2020); and
 - from 2021 to 2022.
- The performance review of the industry's development includes its investment trends, export and import dynamics, employment figures, value-added and productivity measures.

3. Trends and Opportunities

- This section highlights the opportunities and potential avenues for growth that the industry can leverage during the NIMP 2030 period.

4. Challenges

- This section provides insights into potential obstacles that could impact the industry's growth and development.

5. Strategies and Action Plans

- The final section of the document outlines the future trajectory for the industry.
- This section provides the Strategies and Action Plans that are intended to catalyse the industry during the NIMP 2030 period.
- The Strategies and Action Plans set in this Document have been aligned to the Missions set in the main NIMP 2030 document.

¹ Incentives available for this industry as of time of writing can be found in Appendix 1

SECTION 1 BACKGROUND

Areas Covered

- The focus areas of the medical devices industry for this NIMP 2030 are as follows:

Table 5.1: Focus Areas of Medical Devices Industry

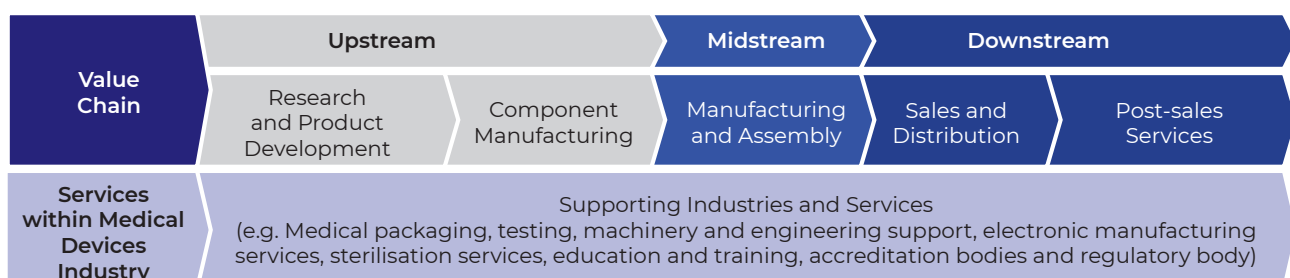
Focus Areas	Examples (Non-exhaustive)
Consumables	<ul style="list-style-type: none"> Single-use devices such as <ul style="list-style-type: none"> Medical gloves Personal Protective Equipment (PPE) Catheters
Surgical instruments, implants and clinical devices	<ul style="list-style-type: none"> Orthopaedic implants Bone grafts Dental implants
Health equipment	<ul style="list-style-type: none"> Ultrasound devices Magnetic Resonance Imaging (MRI) Blood management devices
Point of care	<ul style="list-style-type: none"> Pulse monitors Urine dipsticks Pregnancy tests In-Vitro Diagnostics (IVD)
Non and minimal invasive products	<ul style="list-style-type: none"> Blood glucose monitoring systems Smart surgical devices or tools Intervention devices
Medical devices from convergence of technologies (e.g. biological science, nanotechnology)	<ul style="list-style-type: none"> Drug-eluting stent (DES)

Source: Ministry of Investment, Trade and Industry (MITI)

Value Chain

- The medical devices value chain can be divided into five key areas (Figure 5.1):
 - research and product development – collaboration among universities, research institutes and companies to integrate emerging technologies (e.g. information and communications technology (ICT) and Internet of Things (IoT));
 - component manufacturing – local players and MNC manufacture parts and components to be used as medical parts for the manufacture of medical device products;
 - manufacture and assembly of medical devices;
 - sales and distribution in domestic and foreign markets; and
 - post-sales services including training and maintenance for products (e.g. healthcare equipment).

Figure 5.1: Value Chain of Medical Devices



Source: MITI

3. The industry is supported by services and other infrastructure, which includes but are not limited to:
 - i. sterilisation;
 - ii. clean room services;
 - iii. medical packaging;
 - iv. testing, calibration and maintenance;
 - v. engineering support services;
 - vi. electronic manufacturing services (EMS);
 - vii. plastic injection moulded parts;
 - viii. latex and rubber parts;
 - ix. warehousing and logistics;
 - x. distribution;
 - xi. education and training;
 - xii. accreditation bodies (i.e. Department of Standards Malaysia); and
 - xiii. regulatory bodies (i.e. Medical Device Authority (MDA)).

Market Players

4. In 2022, 536 medical device manufacturers were approved the Manufacturing Licence (ML) by MIDA. Of these, 329 (61.4 per cent) companies were in production (CIP).
5. In 2022, there were 199 local manufacturers licensed by MDA. Any establishment² is required to apply for the license under Medical Device Act 2012 before it can import, export or sell any registered medical device in the local market.
6. Currently, the industry players in Malaysia are concentrated in consumable products such as medical gloves and catheters, followed by surgical instruments, implants and clinical devices (Figure 5.2).
7. The industry was undergoing a transition as more players are involved in the production of higher value-added and technologically advanced products such as cardiac pacemakers, stents, orthopaedic implantable devices, electro-medical, therapeutic and monitoring devices.

² Refers to a person who is either a manufacturer, importer or distributor who is responsible for placing any medical device in the market but does not include a retailer; and an authorised representative appointed by a manufacturer having a principal place of business outside Malaysia

Figure 5.2: Presence of Industry Players along the Value Chain of Medical Devices

		Value Chain				
		Research and Product Development	Component Manufacturing	Manufacturing and Assembly	Sales and Distribution	Post-sales Services
Sub-Sectors	Consumables	High Presence	High Presence	High Presence	High Presence	High Presence
	Surgical Instruments, Implants and Clinical Devices	Medium Presence	Medium Presence	Medium Presence	Medium Presence	Medium Presence
	Health Equipment	Low Presence	Low Presence	Low Presence	Low Presence	Low Presence
	Point of Care	Low Presence	Low Presence	Low Presence	Low Presence	Low Presence
	Non and Minimal Invasive Products	Low Presence	Low Presence	Low Presence	Low Presence	Low Presence
	Medical Devices from Convergence of Technology	Low Presence	Low Presence	Low Presence	Low Presence	Low Presence

Source: MIDA

8. Apart from industry players, industry associations in Malaysia's medical devices industry play a vital role in promoting the interests and growth of the industry, including:
 - i. Malaysian Medical Devices Manufacturers Association (PERANTIM);
 - ii. Association of Malaysian Medical Industries (AMMI);
 - iii. Malaysia Medical Device Association (MMDA);
 - iv. Malaysia Dental Industry Association (MDIA); and
 - v. Malaysian Rubber Glove Manufacturers Association (MARGMA).
9. MDA is a federal statutory agency under the Ministry of Health Malaysia (MOH) which regulates Malaysian medical devices. MDA is entrusted to enforce the Medical Device Act 2012 to address public health and safety issues related to medical devices and facilitate medical device trade and industry.
10. Ministries and Government Agencies which play important parts in developing the industry, including:
 - i. Ministry of Health (MOH);
 - ii. Ministry of Investment, Trade and Industry (MITI);
 - iii. Malaysian Investment Development Authority (MIDA); and
 - iv. Malaysia External Trade Development Corporation (MATRADE).

Policies, Laws and Regulations

11. Law related to the medical devices industry is Medical Device Act 2012.

SECTION 2 PERFORMANCE

IMP3 Focus and Performance

12. During the period of the IMP3 (2006 to 2020), the medical devices industry was focused on several areas including:
 - i. broadening the range of products towards the higher-end category;
 - ii. promoting Foreign Direct Investments (FDI) and Domestic Direct Investments (DDI) in the industry;
 - iii. expanding range of supporting industries and services for the industry; and
 - iv. strengthening the institutional support to enhance human resource development, research and development (R&D) and compliance to international standards and regulations.
 - v. Malaysia was the largest producer and exporter of rubber gloves, contributing 67.0 per cent of global supply, and the world's second largest producer of condoms and rubber thread.
13. During this period, the medical devices industry experienced significant growth driven by the:
 - i. ageing population;
 - ii. increased health awareness and willingness to spend on healthcare from the middle-income class;
 - iii. rising number of chronic diseases such as cardiovascular diseases; and
 - iv. emergence of a strong manufacturing ecosystem which includes EMS and engineering supporting services.
14. Malaysia emerged as Asia's leading manufacturer and exporter of consumables during this period as:
 - i. Malaysia contributed to 80.0 per cent of catheters and 60.0 per cent of rubber gloves to the global market; and
 - ii. the production of rubber gloves increased from 55 billion pairs in 2019 to 102 billion pairs in 2020, growing at a rate of 85.0 per cent.
15. Apart from that, Malaysia became one of the region's top offshore manufacturing hubs for medical devices, producing a broad range of high value medical devices such as:
 - i. orthopaedic products including implants;
 - ii. pacemakers;
 - iii. endoscopy;
 - iv. advanced medical systems; and
 - v. stent and balloon for angioplasty.

Investments

16. The investment performance of the medical devices industry for the period of 2006 to 2022 is recorded in Table 5.2 below.

Table 5.2: Approved Investments of Medical Devices Industry

Items	Units	IMP3			2021	2022	2021-2022
		2006	2020	2006-2020			
Total Investment	RM billion	1.1	6.1	33.4	7.7	8.2	15.9
Domestic Investment	RM billion	0.4	3.9	16.2	4.7	3.2	7.9
Foreign Investment	RM billion	0.7	2.2	17.2	3.0	5.0	8.0
Number of projects	#	29	51	478	38	39	77
Employment	persons	3,788	11,409	100,085	12,498	10,452	22,950

Source: MIDA

17. During the IMP3 period, a total of 478 projects were approved in the medical devices industry with a total investment of RM33.4 billion. These investments committed a total of 100,085 job opportunities.
18. In 2021 and 2022, a total of 77 projects were approved with a total investment of RM15.9 billion. These investments committed a total of 22,950 job opportunities.
19. The investment trend was attributed to the:
- presence of global multinational corporations (MNC) in Malaysia;
 - strong supporting industry clusters including EMS, engineering supporting services, plastics and rubber; and
 - harmonised medical device regulation, as well as standardised technical documents and classification system.
20. From 2006 to 2022, 465 (83.8 per cent) of the 555 approved projects were implemented.

Exports

21. The export performance of the medical devices industry during the period of 2006 to 2022 is recorded in Table 5.3 below.

Table 5.3: Exports of Medical Devices Industry

Item	IMP3			2021	2022	2006-2020	2020-2021	2021-2022
	2006	2020	2006-2020			CAGR	Annual Growth	
Exports (RM billion)	7.1	30.3	227.7	41.4	31.1	10.9%	36.6%	-24.8%

Source: MATRADE

22. During the IMP3 period, the industry's total exports grew by a CAGR of 10.9 per cent, from RM7.1 billion (2006) to RM30.3 billion (2020).

23. In 2021, exports grew significantly by 36.6 per cent to RM41.4 billion. Exports normalised to RM31.1 billion in 2022.
24. Overall, the growth in export was driven by the increased global demand of medical devices such as gloves, face masks and PPE – especially during the COVID-19 pandemic. As countries started to recover with the increasing vaccination rates, the demand for these products normalised in 2022.
25. In 2022, top export destinations were:
- United States (US) (RM9.0 billion, 28.8 per cent);
 - Germany (RM3.5 billion, 11.2 per cent);
 - Belgium (RM2.7 billion, 8.7 per cent);
 - Singapore (RM2.0 billion, 6.4 per cent); and
 - Japan (RM2.0 billion, 6.4 per cent).
26. In 2022, top exported medical devices product were:
- gloves, mittens and mitts for medical, surgical, dental or veterinary purposes (RM6.9 billion, 22.2 per cent);
 - needles, catheters and cannulae (RM5.2 billion, 16.9 per cent);
 - rubber gloves (RM4.8 billion, 15.5 per cent);
 - orthopaedic and other appliances (RM3.5 billion, 11.3 per cent); and
 - instruments and appliances used in medical or veterinary sciences (RM3.0 billion, 9.8 per cent).

Imports

27. The import performance of the medical devices industry during the period of 2006 to 2022 is recorded in Table 5.4 below.

Table 5.4: Imports of Medical Devices Industry

Item	IMP3			2021	2022	2006-2020 CAGR	2020-2021 Annual Growth	2021-2022
	2006	2020	2006-2020					
Imports (RM billion)	1.8	6.8	58.0	6.7	8.2	9.7%	-1.4%	22.5%

Source: MATRADE

28. During the IMP3 period, the industry's imports grew by a CAGR of 9.7 per cent, from RM1.8 billion (2006) to RM6.8 billion (2020).
29. Imports declined by 1.4 per cent to RM6.7 billion in 2021 and increased by 22.5 per cent to RM8.2 billion in the following year.
30. Malaysia was highly dependent on high-tech medical devices from other countries. As such, increased healthcare demand resulted in higher imports.

31. In 2022, top import destinations were:
- US (RM1.4 billion, 17.4 per cent);
 - China (RM1.2 billion, 14.1 per cent);
 - Singapore (RM1.0 billion, 11.9 per cent);
 - Germany (RM0.8 billion, 9.7 per cent); and
 - Japan (RM0.7 billion, 8.9 per cent).
32. In 2022, top imported medical devices products were:
- instruments and appliances used in medical or veterinary sciences (RM1.6 billion, 19.0 per cent);
 - needles, catheters and cannulae (RM1.2 billion, 14.7 per cent);
 - electro-diagnostic apparatus (RM0.7 billion, 8.2 per cent);
 - orthopaedic and other appliances (RM0.5 billion, 6.1 per cent); and
 - contact lenses (RM0.5 billion, 6.1 per cent).

Value-added

33. The value-added (Gross Domestic Product (GDP)) of the medical devices industry for the period of 2006 to 2022 is recorded in Table 5.5 below.

Table 5.5: Value-added of Medical Devices Industry

Item	IMP3		2021	2022	2006-2020	2020-2021	2021-2022
	2006	2020			CAGR	Annual Growth	
Value-added³ (RM billion)	1.5	2.0	2.4	2.0	2.2%	17.6%	-14.0%

Source: Department of Statistics Malaysia (DOSM)

34. During the IMP3 period, the industry's GDP grew by a CAGR of 2.2 per cent from RM1.5 billion in 2006 to RM2.0 billion in 2020.
35. In 2021, the industry's GDP grew significantly by 17.6 per cent to reach RM2.4 billion. The GDP normalised to RM2.0 billion in 2022.
36. Throughout the period, the GDP growth was driven by the increased demand for medical devices – accelerated by the pandemic. As the nation recovered, the demand normalised and returned to pre-pandemic level.

Employment

37. The employment in the medical devices industry for the period of 2019 to 2022 is recorded in Table 5.6.

³ Value-added is measured by the GDP of the industry; 2006 GDP data is based on constant 2005 prices, while 2020 to 2022 data are based on constant 2015 prices

Table 5.6: Employment in Medical Devices Industry

Item	IMP3		2021	2022	2019-2022
	2019	2020			CAGR
Employment ⁴ (persons)	13,359	12,909	12,927	13,120	-0.6%

Source: DOSM

38. The medical devices industry's employment remained relatively constant across four years, from 13,359 persons (2019) to 13,120 persons (2022).
39. The industry employment, which was affected by COVID-19 pandemic was slowly recovering to its pre-pandemic level in 2022.

Labour Productivity

40. The labour productivity of the medical devices industry is recorded in Table 5.7 below.

Table 5.7: Labour Productivity of Medical Devices Industry

Item	IMP3		2021	2022	2019-2022
	2019	2020			CAGR
Labour Productivity ⁵ (RM)	163,234	155,528	182,710	154,775	-1.8%

Source: DOSM

41. The industry's labour productivity declined by a CAGR of 1.8 per cent from RM163,234 (2019) to RM154,775 (2022).
42. The decline in labour productivity was attributed to reduced output resulting from the short-term surge in demand caused by the pandemic in 2021.

Research and Development

43. The R&D activities undertaken by companies in Malaysia include design and development which encompass improvement in the manufacturing process, raw materials and product design.
44. The prominent R&D focus areas were directed towards cardiac rhythm management which included pacemakers, defibrillators, leads and parts and components.
45. The Malaysian Research Accelerator for Technology and Innovation (MRANTI) set up the National Technology and Innovation Sandbox (NTIS) initiative in 2020 to encourage more local R&D activities.
- The initiative was carried out in collaboration with the MOH.
 - Five hospitals have been identified as health technology hubs to accelerate the development, application and commercialisation of local technology and innovation in the healthcare sector.
 - The initiative is currently ongoing to spur local start-ups and innovators to develop innovative solutions and venture into new key focus areas.

⁴This employment data is based on Monthly Manufacturing Statistics December 2022. Due to the change in methodology for employment statistics tabulation in 2019, industry's employment breakdown from 2006 to 2018 is not available

⁵ Annual labour productivity is derived from value added per employment

SECTION 3 TRENDS AND OPPORTUNITIES

46. By 2030, the global market size of medical devices industry is expected to reach nearly RM3.4 trillion⁶, with an annual growth of over 5.0 per cent.⁷
47. This will be driven by the industry moving up the value chain to focus on production of higher value-added medical devices, such as:
 - i. robotics surgical equipment;
 - ii. cardiovascular devices; and
 - iii. point-of-care products (e.g. wearable devices).
48. As part of focusing on high value-added devices, there are opportunities to improve global presence by enhancing data sharing and the cyber security of these devices.

Data Management and Security

49. Preventative and personalised care is the new way of treatment due to the ageing society, rising health awareness and increasing chronic diseases.
50. The demand for personalised care medical devices such as wearable and other connected devices is expected to grow. By 2030, the global wearable technology market size is expected to hit RM833.7 billion⁸, with a growth rate of 15.0 per cent.⁹
51. Technology advancement promotes the adoption of these medical devices.
 - i. Storage and sharing of patients' personal health data are facilitated by digital health technologies such as patient portals, online platforms and mobile applications.
 - ii. Healthcare providers can access patients' information, track vital signs and monitor patients' condition in real time.
 - iii. The data collected can be used for continuous product improvement.
52. However, as these devices collect a wide range of personal data, the widespread adoption of these devices raises the importance of data management and security.
 - i. All users should be fully aware about how their data is collected, used, shared and stored.
 - ii. A necessity for cybersecurity and risk management measure exists to safeguard users against unauthorised access, use or disclosure.
 - iii. It is essential to establish mechanisms to ensure accountability on organisation or healthcare providers that collect and utilise the data.
53. Malaysia has opportunities to explore further in areas including:
 - i. standardisation and interoperability of data to allow seamless data sharing and analytics across different systems; and
 - ii. data security and privacy.
54. Refer to Action Plan 4 (AP4) and Action Plan 5 (AP5) in Section 5 for strategies and action plans related to data sharing and security.

⁶ USD745.0 billion, converted based on exchange rate USD1 to RM4.48

⁷ Source: Research and Markets

⁸ USD186.1 billion, converted based on exchange rate USD1 to RM4.48

⁹ Source: Grand View Research

Global Presence and Regulatory Advantage

55. Malaysia has a strong global presence in the global medical devices industry and this is attributed to its harmonised standards that align to the global requirements.
56. Regulatory harmonisation has expanded market access for local medical device manufacturers. Malaysia is recognised globally as one of the world's leading manufacturers for selected medical devices such as gloves and catheters.
57. MDA plays a vital role in regulating the safety and quality of medical devices and ensuring products with global requirements.
58. A regulated environment provides strong foundation for local manufacturers to compete with foreign industry players, especially while tapping into new emerging markets.

SECTION 4 CHALLENGES

Local Participation in Global Value Chain

59. BMedical devices are highly regulated due to their impact on human health and life. As such, strong emphasis on regulatory compliance are critically required.
60. However, this may pose as a challenge for SME to enter to the market as they have limited resources and expertise to meet the regulatory requirements.
61. Malaysian companies are still facing issues in exporting overseas as several countries such as Japan and Australia do not recognise Malaysia's regulatory approval for medical devices – Malaysian companies are unable to export their products despite being recognised by MDA.
62. Apart from that, the emergence of e-commerce has increased the distribution of unregulated and unauthorised medical devices in Malaysia – especially during COVID-19 when there was an increase demand for oximeters and test kits.
63. To address this challenge, the country can empower a regulatory body like MDA to support local companies in fulfilling both the local and global regulatory requirements. These regulatory bodies can support local companies by:
 - i. streamlining regulatory processes;
 - ii. providing guidance on regulatory compliance and quality standards; and
 - iii. tackling issues on unregulated and unauthorised distribution of medical devices.
64. Refer to Action Plan 2 (AP2) in Section 5 for strategies and action plans related to empowering the regulatory body for regulatory compliance.

Global Presence for Key Growth Products

65. Despite Malaysia being one of the largest exporters of medical devices, the production of high-tech and advance medical devices such as health equipment, non and minimally invasive products are still limited among companies in Malaysia.
66. However, the production of these medical devices are gaining traction reflected by the growth in orthopaedics, in-vitro diagnostic devices and cardiac minimally invasive products globally.
67. Several areas must be addressed to support the access of Malaysia's medical devices to the global markets. These include:
 - i. mutual recognition of requirements; and
 - ii. awareness and knowledge in new global regulations.
68. The following efforts are critical to address the challenges, which include.
 - i. Forming mutual recognition agreements with key markets.
 - ii. Engaging global organisations such as World Health Organization (WHO) for cross-border partnerships with MNC and local industry players.
69. Refer to Action Plan 3 (AP3) in Section 5 for strategies and action plans related to strengthening international relations and supporting industry participation in global events.

R&D Ecosystem

70. Currently, most of the R&D activities by MNCs are conducted in their home countries. The imposition of the global minimum tax would make it less attractive for MNCs to invest in other countries, including Malaysia, as investors would no longer be able to benefit from the lower tax rates offered by these countries.
71. Apart from that, the innovation support system in Malaysia faces structural issues in form of limited funding, insufficient skilled talents and lack of industry exposure.
 - i. The funding and grants are limited to support the development of new product and innovation. The funds may be fragmented across various organisations, agencies and programmes, causing confusion among companies on the funds that can be accessed. These funds are also given based on mutual exclusivity to avoid duplication for the same R&D activities.
 - ii. There are insufficient collaborative research activities between the public and private sectors, limiting data and knowledge sharing for R&D purposes.
 - iii. Talent pool is limited as there is shortage of students pursuing science, technology, engineering and mathematics (STEM) related fields in local universities.
 - iv. In terms of institutional support, pre-clinical testing laboratory is limited domestically. Local players are required to conduct pre-clinical testing overseas to ensure safety and standards of their medical devices.
72. A more comprehensive support system is required to address these limitations and support local innovation, including:
 - i. provide more alternative financing options such as private equity and debt financing at low interest rate for FDI and DDI that conduct innovation;
 - ii. build a stronger talent pool by increasing the awareness of students and attracting skilled researchers and engineers; and
 - iii. enhance integration of research institutes, regulatory body and health technology assessment (HTA) as well as other industry partners to allow data and knowledge sharing as well as to strengthen the ecosystem.
73. Refer to Action Plan 1 (AP1) in Section 5 for strategies and action plans related to developing a stronger structural support for industry players.

SECTION 5 STRATEGIES AND ACTION PLANS

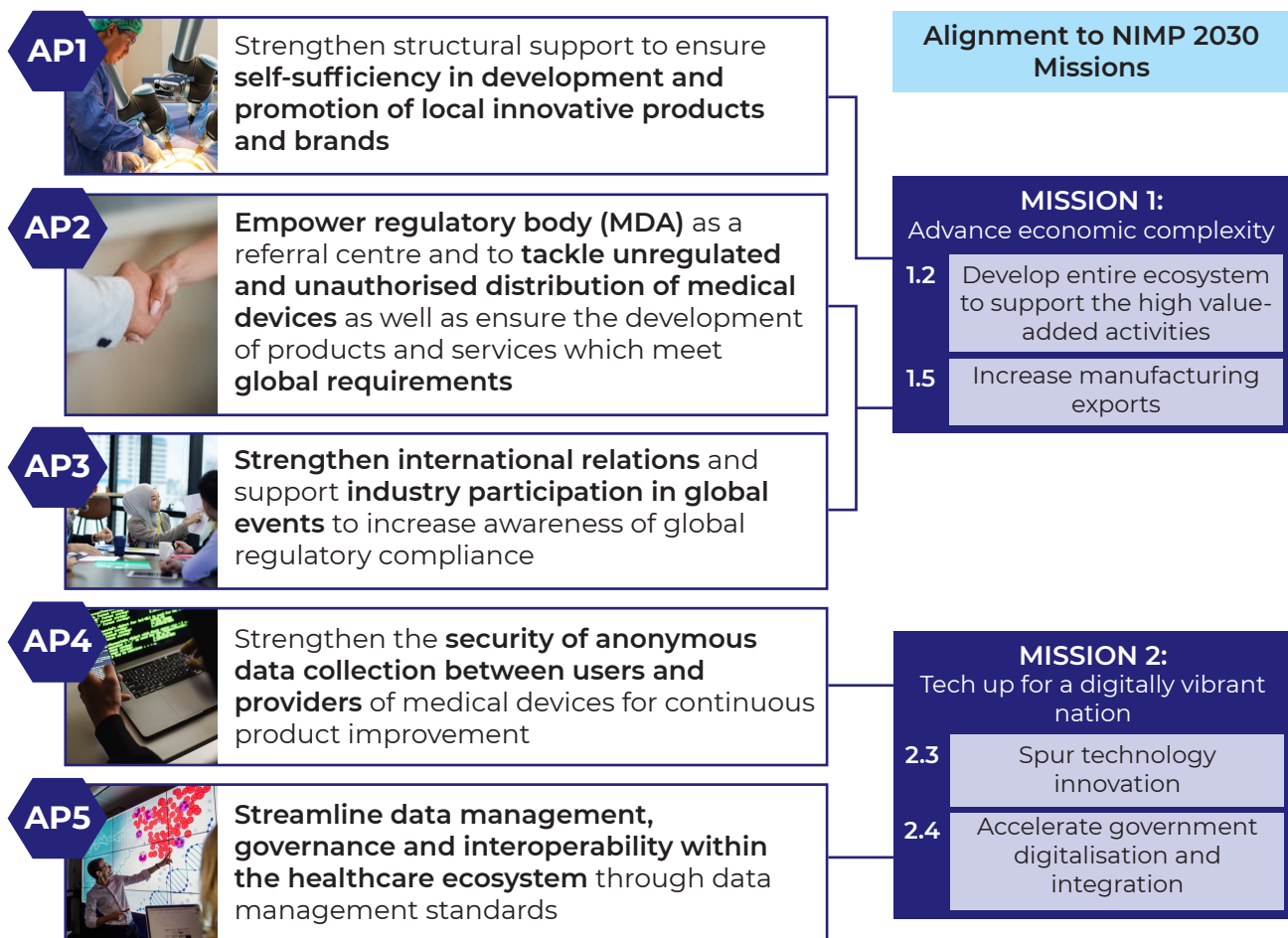
NIMP 2030 Focus

74. During the period of the NIMP 2030, the industry will continue to:
- expand the local market and ensure self-sufficiency by developing higher value-added product and services;
 - increase exports by producing product and services with standards in line with global requirements and regulatory compliance; and
 - adopt the latest technology and systems for product improvement and development.

Action Plans

75. Strategies and Action Plans relating to the NIMP 2030's Missions and Enablers are applicable to this industry (Figure 5.3).

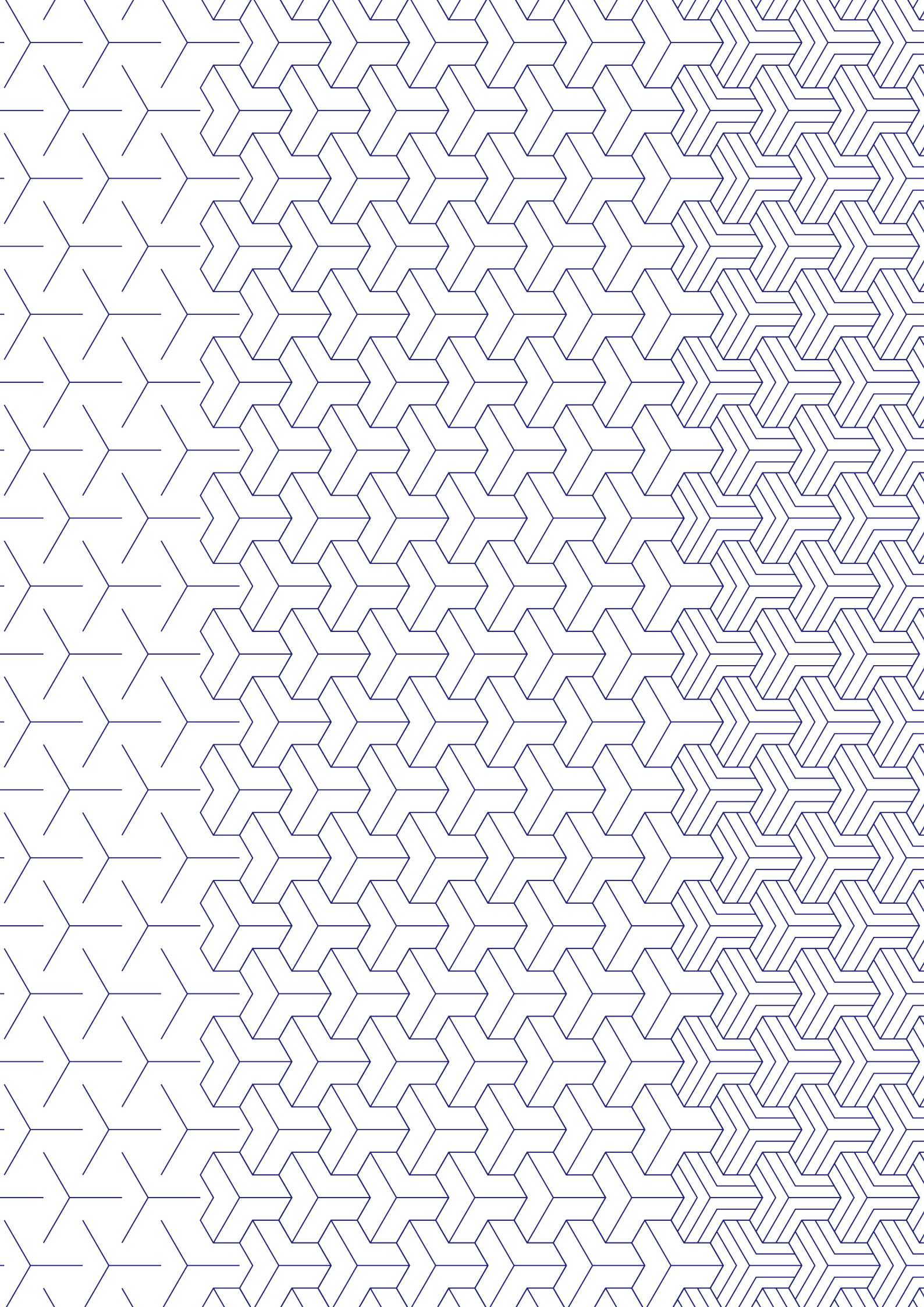
Figure 5.3: Strategies and Action Plans for Medical Devices Industry

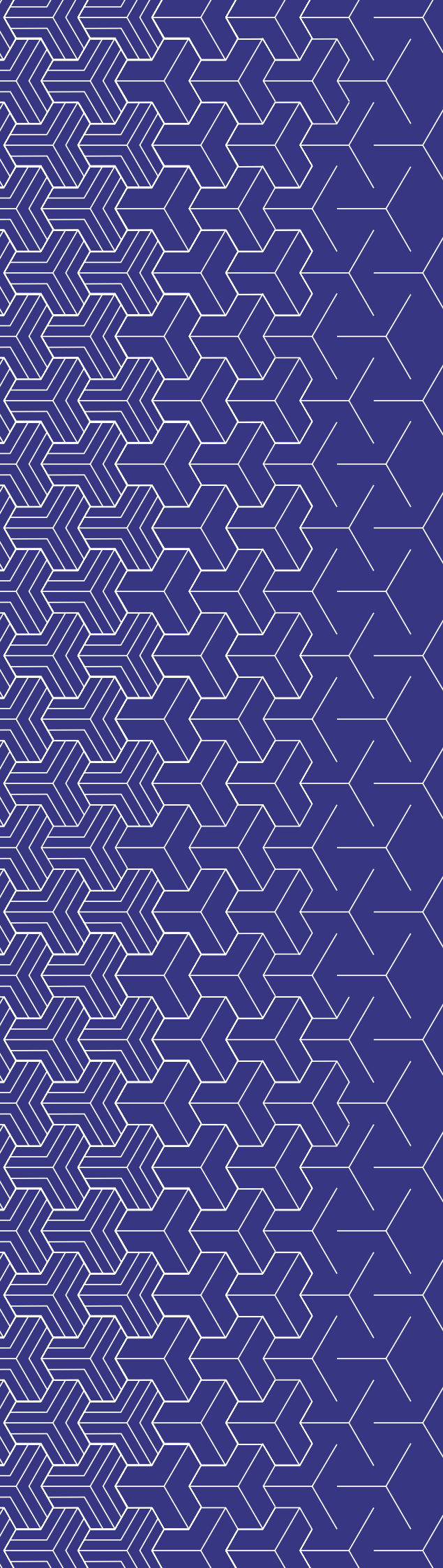


APPENDIX 1 INCENTIVES

There is an array of incentives offered for key players of the medical devices industry, these include the following:

Incentives	Agency
Incentives for General Investment	Malaysian Investment Development Authority (MIDA)
Incentives for High Technology Projects	
Incentives for Strategic Projects	
Incentive for Research and Development (R&D): <ul style="list-style-type: none"> • In-House R&D • Contract R&D Company • R&D Company 	
Commercialisation of Public Sector R&D Findings in Resource-based and Non-Resource-Based Industries	
Incentive for Automation Capital Allowance (Automation CA)	
Special Tax Incentive (Relocation)	
Import Duty and/or Sales Tax Exemption on Machinery/ Equipment/ Raw Materials/ Components	
Reinvestment Allowance	Inland Revenue Board of Malaysia (LHDN)





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