AndamanMedical
Regulatory affairs & market access

Navigating Your Opportunities to Launch in Southeast Asia

尋找在東南亞開展業務的機會?

Your Premier Partner, Streamlining Your Regulatory Compliance Processes

您的東南亞醫療器材註冊的首要合作夥伴

www.andamanmed.com

Content

1. **Your roadmap for the medical device regulatory framework in Southeast Asia.**
   了解您的產品在東南亞醫療器材監管方面的法規架構。

2. **Your opportunities as a manufacturer in this dynamic market - are you ready?**
   身為製造商，您準備好面臨東南亞市場的機會嗎？

3. **Navigating regulatory challenges together!**
   讓我們與您共同應對監管挑戰！

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Presenter of The Day

Tan Shouzheng

Head of Sales

Company: Andaman Medical Pte Ltd
Contact: shouzheng@andamanmed.com
Years in the industry: 7 years
Experiences:
I started in a regulatory affairs role for medical device registration in Malaysia and Singapore, including technical file preparation, managing change assessment, and post-market activities for various medical devices. Involved in implementing Quality Management Systems (QMS). Currently working as the Head of Sales for Andaman Medical, overseeing Southeast Asia countries, including Singapore, Malaysia, the Philippines, Indonesia, Thailand, Vietnam, and Cambodia, developing regulatory strategies for medical device manufacturers to enter the markets.
Background:
Bachelor of Engineering (Honours) (Bioprocess Engineering), Biochemical Engineering

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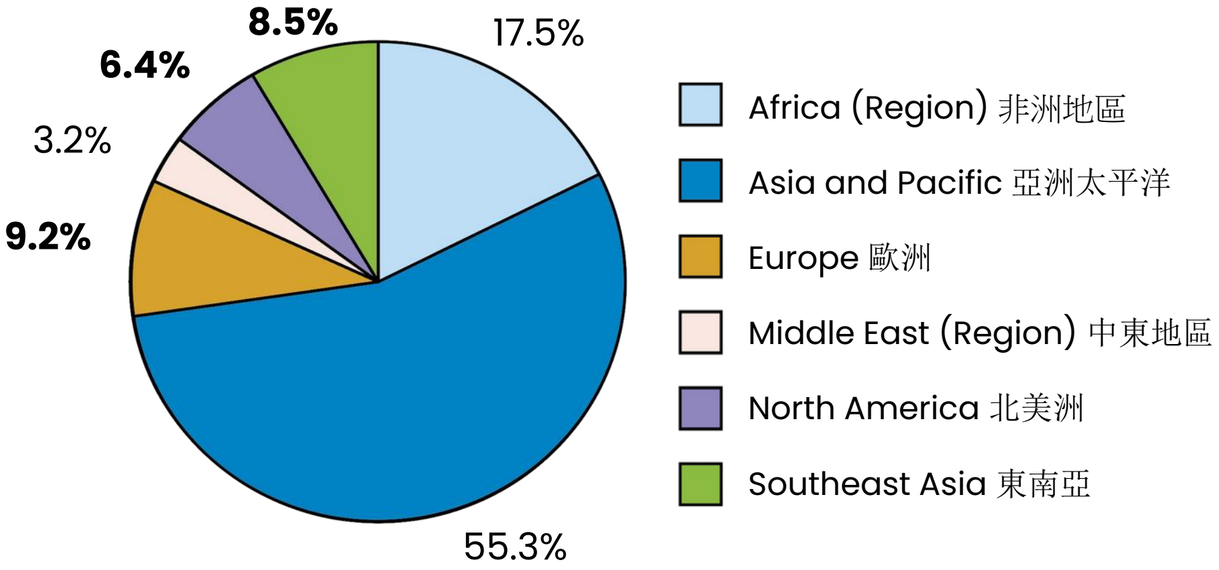
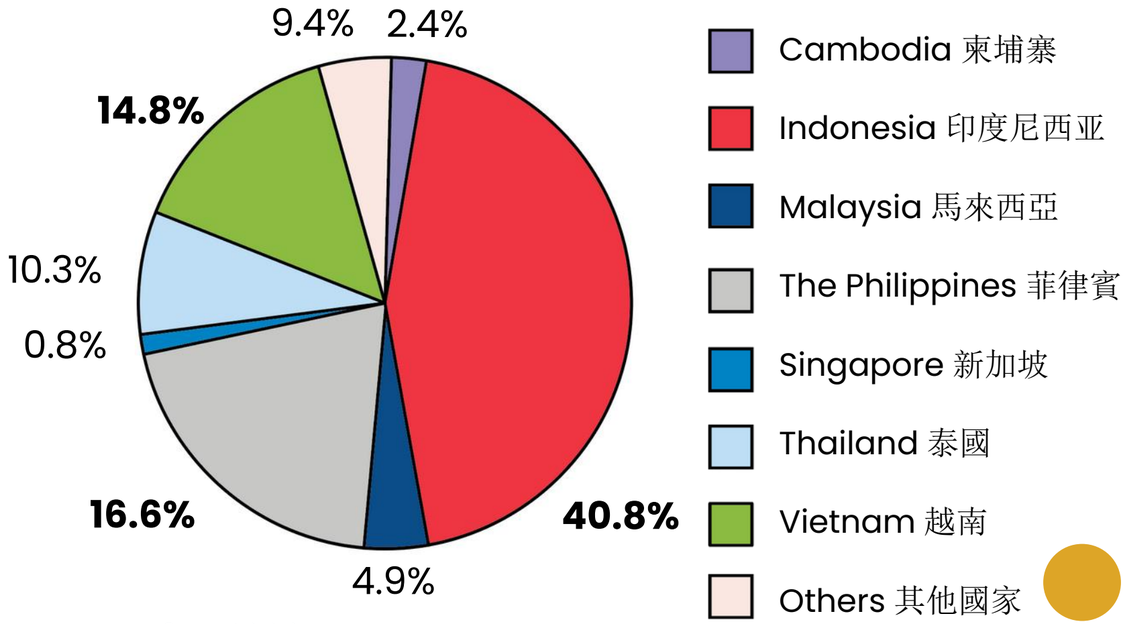
Population Overview

Global Population by Region 全球各地區人口



Southeast Asia Population by Country 東南亞各地區人口



Analysis 分析：

- SEA, with 680 million people, is a crucial global market. Indonesia leads SEA, followed by Vietnam, the Philippines, and Thailand.
- Europe has 733 million people. The combined populations of Indonesia, Vietnam, and the Philippines are already 500 million, nearing North America's population of 510 million.
- 擁有 **6.8** 億人口的東南亞是至關重要的全球市場。 印尼在東南亞地區居首位，其次是越南、菲律賓和泰國。
- 發展地區歐洲和北美洲的人口分別是**7.3**億和**5.1**億。東南亞三個國家**-**印度尼西亞，越南，和菲律賓的總人口已達**5**億人口，並逐漸逼近北美洲。

Verdict 結論：

- High population -> more elderly -> more medical care needed.
- SEA countries adopting universal healthcare -> better health awareness.
- 人口多 **->** 人口老化**->**人民需要更多的醫療服務。
- 東南亞國家採用全民健保制度 **->** 促使人民擁有更強的健康意識。

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Medical Device Risk Classification

醫療器材風險分類

Class – Risk Level 類別 - 風險等級	General Medical Devices (GMDs) 醫療器材	In-Vitro Diagnostics Devices (IVDs) 體外診斷器材
A - Low Risk 低風險	Simple Surgical instruments, Stethoscopes 簡單手術器械、聽診器	Clinical Chemistry Analyzer 臨床化學分析儀
B - Low Moderate 中低風險	Phototherapy Unit, Aspirator 光療器、吸入器	Pregnancy Self-Testing 妊娠自我檢測
C - High Moderate 中度偏高風險	Orthopedic implants, Lung Ventilator 骨科植入物、肺部通氣器	Blood Glucose Self-Testing 血糖自我檢測
D - High Risk 高風險	Pacemakers, Neurological Catheters 心臟節律器、神經導管	HIV Blood Donor Screening HIV 捐血者篩檢

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Medical Device Grouping

醫療器材分組

	SINGLE 單一	SYSTEM 系統	FAMILY 系列	SET 套裝	IVD TEST KIT IVD 測試套件	IVD CLUSTER IVD 群組
Indonesia 印度尼西亚	No implementation yet. Maximum 500 accessories/product codes in one application. 尚未實施。一個申請中最多 500 個配件/產品代碼。					
Malaysia 馬來西亞	✓	✓	✓	✓	✓	✓
Vietnam 越南	✓	✓	✓	✓	✓	✓
The Philippines 菲律賓	No implementation yet. Each product needs to be registered separately. One application multiple CMDR scheme exist following its criteria. 尚未实施。每个产品需要单独注册。允许一次申请中呈交多项CMDR条项，但还需依据当局标准而定。					
Singapore 新加坡	✓	✓	✓	✓	✓	✓
Thailand 泰國	✓	✓	✓	✓	✓	✓
Cambodia 柬埔寨	No implementation yet. Each product needs to be registered separately. 尚未實施。每個產品需要單獨註冊。					

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Medical Device Registration Timeline – Government 醫療器械註冊時間表 - 政府

Without approvals Australia Therapeutic Goods Administration (TGA), European Union Notified Bodies (EU NB), Health Canada (HC), Japan Ministry of Health, Labour and Welfare (MHLW), US Food and Drug Administration (US FDA).

若還未擁有下列機構準證： 澳洲醫療用品管理局 (TGA)、歐盟公告機構 (EU NB)、加拿大衛生部 (HC)、日本厚生勞動省 (MHLW)、美國食品藥物管理局 (US FDA)。

With Approval From Taiwan Food and Drug Administration (TFDA)
持有台灣福利部食品藥物管理署 (TFDA) 批准

	CLASS A	CLASS B	CLASS C	CLASS D
Indonesia 印度尼西亚	45 working days	60 working days	60 working days	80 working days
Malaysia 馬來西亞	1 – 2 months	9 – 12 months (including timeline for conformity assessment) 包括合規性評估時間表	9 – 12 months (including timeline for conformity assessment) 包括合規性評估時間表	9 – 12 months (including timeline for conformity assessment) 包括合規性評估時間表
Vietnam 越南	15 – 30 calendar days	15 – 30 calendar days	9 – 12 months (est)	9 – 12 months (est)
The Philippines 菲律賓	4 – 6 months	CMDN: 4 – 6 months CMDR: 9 – 12 months	CMDN: 4 – 6 months CMDR: 9 – 12 months	CMDN: 4 – 6 months CMDR: 9 – 12 months
Singapore 新加坡	Exempted 豁免	160 working days (via full route) 透過完整流程	220 working days (via full route) 透過完整流程	310 working days (via full route) 透過完整流程
Thailand 泰國	1 or 60 calendar days	250 calendar days	250 calendar days	300 calendar days
Cambodia 柬埔寨	12 – 18 months	12 – 18 months	12 – 18 months	12 – 18 months

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Medical Device Registration Timeline – Government 醫療器械註冊時間表 - 政府

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若已擁有下列機構準證: 澳洲醫療用品管理局 (TGA)、歐盟公告機構 (EU NB)、加拿大衛生部 (HC)、日本厚生勞動省 (MHLW)、美國食品藥物管理局 (US FDA)。

	CLASS A	CLASS B	CLASS C	CLASS D
Indonesia 印度尼西亚	45 working days	60 working days	60 working days	80 working days
Malaysia 馬來西亞	1 – 2 months	4 – 6 months (including timeline for conformity assessment) 包括合規性評估時間表	4 – 6 months (including timeline for conformity assessment) 包括合規性評估時間表	4 – 6 months (including timeline for conformity assessment) 包括合規性評估時間表
Vietnam 越南	15 – 30 calendar days	15 – 30 calendar days	9 – 12 months (est)	9 – 12 months (est)
The Philippines 菲律賓	4 – 6 months	CMDN: 4 – 6 months CMDR: 9 – 12 months	CMDN: 4 – 6 months CMDR: 9 – 12 months	CMDN: 4 – 6 months CMDR: 9 – 12 months
Singapore 新加坡	Exempted 豁免	100 working days (via full route) 透過完整流程	160 working days (via full route) 透過完整流程	220 working days (via full route) 透過完整流程
Thailand 泰國	1 or 60 calendar days	250 calendar days	250 calendar days	300 calendar days
Cambodia 柬埔寨	12 – 18 months	12 – 18 months	12 – 18 months	12 – 18 months

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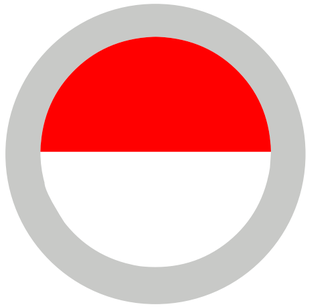
License Validity 許可證有效期限

INDONESIA 印度尼西亚



Minimum of 2 years with a maximum of 5 years. Validity depends on the validity given in the Letter of Authorization.

最短 2 年，最長 5 年。 有效期限取決於授權書中規定的有效期限

MALAYSIA 馬來西亞

5 years

5 年

VIETNAM 越南

No expiration date

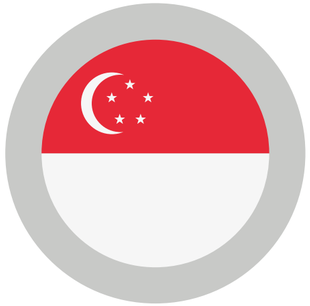
無限

THE PHILIPPINES 菲律賓

5 years. Class B, C, D medical devices that undergo CMDN will have 2 years before transition to CMDR for 5 years.

5 年。 取得 CMDN 證書的 B、C、D 類醫療器材將有 2 年的有效期限，然後過渡到 CMDR，有效期為 5 年

SINGAPORE 新加坡



1 year. Paying retention fee each year to maintain the validity.

無限。 每年繳交保留費，以維持有效期限。

THAILAND 泰國

5 years

5 年

CAMBODIA 柬埔寨

3 years

3 年

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Transferring of Licenses in Southeast Asia 東南亞許可證轉讓

Once the medical device has been registered, in some countries, medical device licenses can be transferred after registration, known as "Change of Ownership". Check the list and the database to search for registered devices.
醫療器材註冊後，在某些國家，醫療器材許可證可以在註冊後轉讓，也就是所謂的「所有權變更」。檢視清單和資料庫，搜尋已註冊的器械。

Indonesia 印度尼西亚	No license transfer. Product shall be registered as new. 不得轉讓許可證。產品應註冊為新產品。號
Malaysia 馬來西亞	Transferring of licenses are allowed but need to obtain the approval from the current license holder. 允許轉讓許可證，但必須獲得目前許可證持有人的批准。
Vietnam 越南	No license transfer. Product shall be registered as new. 不得轉讓許可證。產品應註冊為新產品。
The Philippines 菲律賓	Transferring of licenses are allowed but need to obtain the approval from the current license holder. 允許轉讓許可證，但需獲得目前許可證持有人的批准。
Singapore 新加坡	Transferring of licenses are allowed but need to obtain the approval from the current license holder. 允許轉讓許可證，但必須獲得目前許可證持有人的批准。
Thailand 泰國	No license transfer. Product shall be registered as new. 不得轉讓許可證。產品應註冊為新產品。
Cambodia 柬埔寨	No license transfer. Product shall be registered as new. 不得轉讓許可證。產品應註冊為新產品。

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Regulatory Requirements in Southeast Asia

Common Submission Dossier Template (CSDT) is a format for submitting medical device conformity evidence to EPSP in Southeast Asia. Its elements include :

1. Executive Summary
2. Essential Principles
3. Description of Medical Device (principles of operation, risk class, description of accessories, list of configurations, key functional elements, novel features, intended use, indications, instruction for use, contraindications, warnings, precautions, potential adverse effects, alternative therapy, materials, other relevant information)
4. Summary of Design Verification and Validation Documents (appropriate tests such as engineering tests, laboratory tests, biocompatibility tests, animal tests, simulated
5. use, software validation)
   Preclinical Studies (such as biocompatibility test, software validation studies,
6. medical device containing biological materials)
7. Clinical Evidence
8. Use of Existing Bibliography
9. Labeling
10. Risk Analysis
11. Manufacturing Process
    ISO 13485 Certificate

However, the documents list in each country are country-specific.

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東南亞地區的監管要求

Common Submission Dossier Template (CSDT) 是向東南亞 **EPSP** 提交醫療器械合規性證明的文件格式。其主要文件包括：

1. 內容摘要
2. 基本原理
3. 醫療器材描述（操作原理、風險等級、附件描述、配置清單、關鍵功能要素、新功能、預期用途、適應症、使用說明、禁忌症、警告、預防措施、潛在不良反應、替代療法、材料、其他相關資訊）
4. 設計驗證和確認文件摘要（適當的測試，例如工程測試、實驗室測試、生物相容性測試、動物測試、模擬使用、軟體驗證等）
5. 臨床前研究（例如生物相容性測試、軟體驗證研究、含有生物材料的醫療器材）
6. 臨床證據
7. 使用現有參考書目
8. 標籤
9. 風險分析
10. 製造工藝
11. 證書

註明：每個國家的文件清單都會因國家而異。

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Malaysia 馬來西亞

Opportunities 機會與優勢

- Reference agencies allow fast-track approval, with verification registration.
- 參照機構準證允許快速審批，並進行核實登記。
- Class A approval in 30 days; Class B, C and D approval in 60 days.
- **A** 類核准 **30** 天；**B**、**C** 及 **D** 類核准 **60** 天。
- English documents can be accepted for registration (except for home-use product).
- 註冊可接受英文文件（家用產品除外）。
- Clear regulatory guidance available on Authority's website, easy to navigate.
- 監管機構網站提供清晰的監管指南，易於瀏覽。
- Top two market share together with Thailand among SEA in medical tourism due to cheaper healthcare services.
- 由於醫療保健服務較為便宜，在東南亞醫療旅遊市場中與泰國並列市場份額的前兩位。

Challenges 市場的情況與挑戰

- Full CSDT requirements for submission.
- 對文件提交有完整的 **CSDT** 要求。
- Two regulatory agencies for combination products: MDA for Medical Device; NPRA for Drug.
- 對組合產品有兩個監管機構**: MDA** 負責醫療器材；**NPRA** 負責藥品。
- Reference countries approval is important to determine the registration pathway.
- 參照國的準證對於確定註冊途徑非常重要。

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Singapore 新加坡

Opportunities 機會與優勢

- Reference agencies allow fast-track approval, with abridged registration. 參照機構準證允許快速審批，簡化註冊程序。
- Clear regulatory guidance available on Authority's website, easy to navigate. 監管機構網站提供清晰的監管指南，易於瀏覽。
- Member of International Medical Device Regulators Forum (IMDRF). 國際醫療器材監管機構論壇 (IMDRF) 成員。
- Approvals can fast track the registration in the Philippines and Thailand. 在菲律賓和泰國可快速審批註冊。
- No expiration for product license validity by paying a retention fee yearly, hassle-free with right independent agency. 只要有適當的獨立代理機構，每年支付保留費，產品許可證有效期不會過期，省心省力。
- Singapore continued to be the preferred destination in specialized areas of treatment such as oncology, organ transplants, orthopedics, cardiology, and neurology. 新加坡仍然是腫瘤學、器官移植、整形外科、心臟病學和神經病學等專業治療領域的首選目的地。
- Top aged population in ASEAN. 東協老齡人口最多的國家。

Challenges市場的情況與挑戰

- Full CSDT requirements for submission.
- 要求提交完整的 CSDT。
- High registration cost.
- 註冊費用高。
- Small market due to low population, high living cost.
- 人口少，市場小，生活費用高
- Reference countries approval is important to determine the registration pathway.
- 參照國的批准對於確定註冊途徑非常重要

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Vietnam 越南

Opportunities 機會與優勢

- Fast approval for Class A and B in 14 days
- **14** 天內快速核准 **A** 類別和 **B** 類別。
- No expiration for product license validity, hassle-free with right independent agency.
- 只要有適當的獨立代理機構，產品許可證的有效期不會過期，省心省力。
- 90% of medical equipment in Vietnam is imported, market value at 1.5 billion USD, targeting to reach 2.1 billion by 2026.
- 越南 **90%** 的醫療設備依賴進口，市場價值為 **15** 億美元，目標是到 **2000**億美元。

Challenges 市場的情況與挑戰

- Slow approval for Class C and D, MoH is working to resolve the situation by the appointment of local CABs to assess the application with CSDT only.
- **C** 類和 **D** 類審批僅緩慢，衛生部正在努力解決這一問題，指定當地 **CAB** 透過 **CSDT** 評估申請。
- Shortage of medical infrastructure and medical professionals.
- 醫療基礎設施和醫療專業人員短缺。

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Cambodia 柬埔寨

Opportunities 機會與優勢

- Cambodia's economy develops, increases demand for better quality healthcare services.
- 柬埔寨經濟不斷發展，對高品質醫療服務的需求不斷增加。
- Good opportunity for tender as government is demanding advanced healthcare technology.
- 政府要求提供先進的醫療設備，這為招標提供了良好機會。
- US made drugs and medical equipment are well regarded in Cambodia.
- 美國製造的藥品和醫療設備在柬埔寨廣受好評

Challenges 市場的情況與挑戰

- Slow approval for all classes of medical devices.
- 所有類別的醫療器材審批緩慢。
- Manual registration.
- 人工註冊。
- US made drugs and medical equipment are well regarded in Cambodia.
- 美國製造的藥品和醫療設備在柬埔寨廣受好評。
- Cambodia market very small when compared to other SEA countries, might observe slower return (it is expected to achieve a great growth in future).
- 與其他東南亞國家相比，柬埔寨市場非常小，回報可能較慢（預計未來將實現大幅增長）。

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The Philippines 菲律賓

Opportunities 機會與優勢

- Approvals in Malaysia and Singapore can fast track the registration in the Philippines.
- 在馬來西亞和新加坡獲得準證後，可快速在菲律賓註冊。
- 2nd most populous country in Southeast Asia, after Indonesia.
- 菲律賓是東南亞人口第二多的國家，僅次於印尼。
- Most IVDs are considered non-registrable and can be imported without registration.
- 大部分 **IVD** 是不可註冊的，所以目前無需註冊即可進口。
- The largest market for Cardiology Devices with projected market volume of USD 102.90 in 2024. 菲律賓是最大的心臟病設備市場，預計 **2024** 年的市場容量將達到 **102.90** 美元。
- Implementation of PhilHealth – the national health scheme to make sure all low-income families are well-covered with healthcare treatment in government hospitals. 實施 **PhilHealth** – 國家醫療計劃，確保所有低收入家庭都能在政府醫院獲得良好醫療服務。

Challenges市場的情況與挑戰

- Slow approval for Class B, Class C and Class D medical devices.
- **B** 類、**C** 類和 **D** 類醫療器材核准緩慢。
- New regulation to be implemented by the Philippines FDA to increase the government fee.
- 菲律賓 **FDA** 將實施新規定，提高政府收費。
- Shortage of medical professional (6th largest contributor of doctors and top contributor of nurses to OECD countries).
- 醫療專業人員短缺（在經合組織國家中，醫生派遣國排名第六，護士派遣國排名第一）。

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Thailand 泰國

Opportunities 機會與優勢

- Standard of living in Thailand continues to rise, demand for better healthcare.
- 泰國的生活水準不斷提高，需要更好的醫療保健服務。
- Approval in Singapore can fast track the registration in Thailand.
- 在新加坡取得準證可以快速在泰國註冊。
- In 2022, the value of Thailand's medical device market was approximately $7.2 billion.
- **2022** 年，泰國醫療器材市場價值約為 **72** 億美元。
- Top two market share together with Malaysia among SEA in medical tourism due to cheaper healthcare services.
- 在東南亞醫療旅遊市場，由於其廉價的醫療保健服務，泰國與馬來西亞的市場位居前兩位。
- Second top aged population in ASEAN, after Singapore.
- 東協第二大老人口國，僅次於新加坡。

Challenges市場的情況與挑戰

- Full CSDT requirements for submission.
- 提交申請需符合完整的 **CSDT** 要求。
- Language barrier, Andaman Medical is here to help.
- 語言障礙，**Andaman Medical** 醫療可提供協助。
- Shortage of medical professionals.
- 醫療專業人員短缺。

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Indonesia 印度尼西亚

Opportunities 機會與優勢

- The largest population among ASEAN member countries, with over 270 million people as of December 2023 data, hence it shows significant market potential.
- 東協成員國中人口最多的國家，截至 **2023** 潛力大。
- 7% of Indonesia's population (around 19 million people) are senior population.
- 印尼 **7%** 的人口（約 **1900** 萬）為老年人口。
- Fast approval in maximum 80 working days.
- 最長 **80** 個工作日的快速審核。
- 100% foreign ownership is allowed in Indonesia now.
- 印尼目前允許 **100%** 外資控股
- Purchase of medical device via government hospital via e-Catalogue, transparency on the pricing.
- 透過電子目錄在政府醫院購買醫療器械，價格透明。

Challenges市場的情況與挑戰

- One brand can only be registered by one company in Indonesia, important to focus on an independent license holding.
- 在印尼，一個品牌只能由一家公司註冊，因此必須重視獨立許可證的持有。
- The government encourage the development of the local medical device manufacturing, competitive market.
- 政府鼓勵發展本地醫療器材製造業，市場競爭激烈。
- Language barrier, Andaman Medical is here to help.
- 語言障礙，**Andaman Medical** 可提供協助。
- Difficult access for remote areas.
- 偏遠地區交通不便。
- Implementation of Halal regulation in near future.
- 即將實施清真法規。
- Shortage of medical infrastructure and medica professional.

療基礎設施和醫療專業人員短缺。

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AndamanMedical
Regulatory affairs & market access

INTRODUCTION

YOUR ONE-STOP SOLUTION for Medical Devices Registration in Asia

您的一站式解決方案 亞洲醫療器材註冊

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Our Services

我 們 的 服 務

Medical Devices & IVDs Registration

- Local Regulatory Compliance
- Complete Dossier Preparation and Submission
- Labelling Review
- On-site Follow Up
- Timely Approval

醫療器材和體外診斷器材 (IVD) 註冊

- 當地監理合規性
- 全套文件準備和提交
- 標籤審查
- 現場跟進
- 及時審批

Authorised Representative (AR)

- Local Business Presence
- Full Control towards Registration License
- Flexibility Working with Different Distributor (switching without hassle).
- Post-market Surveillance
- Stay Updated on Regulations

授權代表 (AR)

- 擁有當地公司業務
- 全權控制註冊許可證
- 與各類經銷商靈活合作（無縫切換）。
- 上市後監督
- 隨時了解最新法規

Importation in the Philippines / Indonesia / Thailand

- Required by the Local Regulation Requirement (Authorised Representative to be the importer)
- Importation Compliance
- Customs Clearance
- Record-keeping of the Importation Documents

菲律賓/印尼/泰國進口服務

- 符合當地法規要求（授權代表為進口商）
- 進口合規性
- 清關
- 記錄保存進口文件

Intelligence Reports

- Covered all Regulatory Affairs Topics
- Document Compliance Screening
- Gap Analysis

情報報告

- 涵蓋所有監管事務主題
- 文件合規性篩檢
- 差距分析

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Our Clients Portfolio

我 們 的 客 戶

2000+

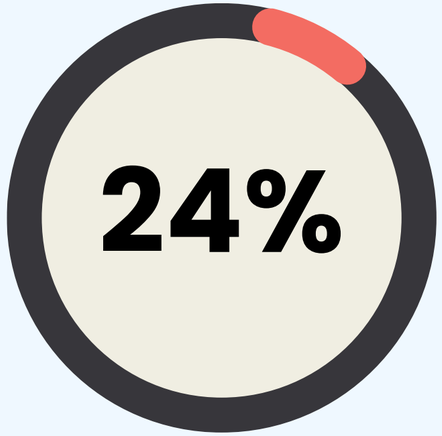
Registered more than 2000+
Medical Devices and IVDs products.

註冊超過 2000+醫療器材和體外診斷器材（IVD）產品。

200+

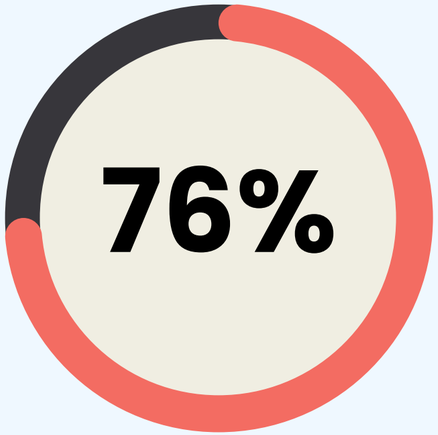
Helped more than 200+ manufacturers
to register their products.

授權代理商 200+ 多家製造商註冊證。



Multinational corporations

跨國企業



SME & Startup

中小型企業和新創企業

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Workflow for Entering Southeast Asia Market

进 入 东 南 亚 市 场 的 工 作 流 程

STEP 1 **Engagement** 客戶接洽	✅ Schedule an online meeting with manufacturer to understand requirements ✅ Proposal given ✅ Review & Signed ✅ Master Service Agreement and Work Order ready	✅ 與製造商安排線上會議，了解需求 ✅ 提出建議 ✅ 審查並簽署 ✅ 準備好主服務協議及工作訂單
STEP 2 **Registration** 產品註冊	✅ Local in-house Regulatory Affairs Specialist takes over to engage in providing document list for registration ✅ Manufacturer submits required technical files ✅ Specialist drafts compliant documents ✅ Reviews & submits to Authority	✅ 當地內部監管事務專家接手提供註冊文件清單 ✅ 製造商提交所需的技術文件 ✅ 專家起草合規文件 ✅ 審查並提交給監管機構
STEP 3 **Authority Review** 監管機構審查	✅ Regulatory Affairs Specialist reviews Authority input and consults manufacturer ✅ Keep tracking Authority progress ✅ Notify the manufacturer of approval	✅ 法規事務專家審查監管機構的意見並諮詢製造商 ✅ 持續跟進監管機構的進展 ✅ 將批准情況通知製造商
STEP 4 **Post-Approval** 上市批准	✅ Authorizes importer/distributor in Malaysia, Singapore, Vietnam, and Cambodia ✅ For the Philippines, Indonesia, and Thailand, we will act as an importer and deliver to a local distributor ✅ Monitors license and post-market compliance	✅ 授權馬來西亞、新加坡、越南和柬埔寨的進口商/分銷商 ✅ 對於菲律賓、印尼和泰國，我們將充當進口商，並將產品交付給當地經銷商 ✅ 監控許可證和上市後合規性

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Why Choose Us

為 何 選 擇 我 們

Experienced In-house Team across 7 Southeast Asia Countries
在東南亞七個國家擁有經驗豐富的內部團隊

QMS Compliance (ISO 13485 Certified)
遵守並擁有合規品質管理體系和 ISO 13485 認證

Full Control with Seamless Distributor Switching
全權控制無縫切換經銷商

Overcome Language Barrier
克服語言障礙

Singular Point of Contact for Registration
提供統一的註冊聯絡人

One-Stop Access into Southeast Asia
一站式方案進入亞洲市場

Our Clients 客 户 评 价

"I've been very happy working with Andaman Medical. Their representatives were very patience and informative throughout the registration process. I highly recommend Andaman Medical for your medical device registration needs.

我與 Andaman Medical 的合作非常愉快。在整個註冊過程中，他們的代表都非常有耐心，而且提供了很多資訊。我強烈推薦 Andaman Medical 滿足您的醫療器材註冊需求。

-Rhonda Allen, Versah LLC-"

"Since appointing Andaman Medical as our partner, their consultants have been great in assisting us in understanding the regulations. Their service has always been prompt and professional. It demonstrates the competence of Andaman Medical. We look forward to a great long-lasting relationship with Andaman Medical.

自從選擇 Andaman Medical 作為我們的合作夥伴以來，他們的顧問表現出色，幫助我們理解相關法規。他們的服務始終迅速而專業。這充分證明了 Andaman Medical 的業務能力。我們期待與 Andaman Medical建立長期的良好合作關係。

-Jonathan Soh, Hitachi Medical-"

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The Philippines
Andaman Medical Philippines Corporation
2nd Floor San Antonio de Padua Building
Lot 1 Block 3 Gloria Diaz corner L.V. Aurelio Street BF Resort Village, Talon Dos Las Piñas City

Indonesia
PT. Andaman Medical Indonesia
Menara Cardig Ist Floor
Jl. Raya Halim Perdanakusuma Jakarta Timur - Indonesia, 13650

Thailand
Andaman Medical (Thailand) Ltd.
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Vietnam
Andaman Medical (Vietnam) Co., Ltd.
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Hanoi, Vietnam
9th floor, Gelex Tower Building, 52 Le Dai Hanh Street, Le Dai Hanh Ward, Hai Ba Trung District, Hanoi, Vietnam.

Cambodia
Andaman Medical (Cambodia) Co., Ltd
CASA by Meridian, Orient Tower, #242, 2nd Floor, No. 1, Harvard Street, Diamond Island, Tonle Bassac, Chumkamorn, Phnom Penh 120101 Cambodia.

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Regulatory affairs & market access

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Thank You

謝謝