APACMed
The voice of MedTech

Modernising FSC/CFG Practices for Efficient Market Access

POSITION PAPER

REGULATORY AFFAIRS

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CONTENTS

EXECUTIVE SUMMARY

APACMed's Position Paper highlights that many regulators still require Free Sale Certificates/ Certificates to Foreign Government (FSC/CFG) for registration and renewal, even though mature systems no longer need them. Some authorities ask for a market authorisation licence (MAL), others for an FSC/CFG, and in some cases both, despite serving the same purpose. A valid MAL from the legal manufacturer's country or a recognised reference authority already confirms legal market placement and acceptable safety and performance. Yet additional certificates, along with notarisation, legalisation/apostille, or hardcopy requirements, continue to be requested, creating unnecessary administrative burden and delaying timely access to approved medical technologies.

This Position Paper maps current practices across APAC, highlights where requirements are duplicative or misaligned with current regulatory capacity, and proposes principles to support more predictable, efficient, and digitally verifiable pathways that maintain safety while improving patient access.

APACMed stands ready to work with regulators and local associations to share data, develop practical transition approaches, and support implementation in a way that reflects each country's needs and context.

INTRODUCTION

1

Free Sale Certificates (FSC), also called Certificates of Free Sale (CFS), and Certificates to Foreign Government (CFG) have traditionally been requested by regulators to confirm that a medical device (MD) or in-vitro diagnostic device (IVD) is legally approved or sold in the country of origin and/or recognised reference authorities. These documents were often used during regulatory submissions to demonstrate that a product met the safety, quality, and performance standards of a recognised reference market.

While these certificates once served a purpose in markets with limited regulatory capacity, many markets across Asia-Pacific have since developed more advanced and independent regulatory systems. A market authorisation licence now typically provides sufficient evidence that a product complies with local regulatory requirements and standards. The criteria of issuing the FSC/CFG from a given country is also based on the market authorisation license and commercialisation in this country, where seeing FSC/CFG is a derivative document of the market authorisation license. As a result, in countries with more mature regulatory systems, FSC/CFG are no longer a mandatory requirement during the registration process. Instead, authorities may rely more on the product's market authorisation license from the country of origin and/or recognised reference authorities or conduct technical review themselves. Nonetheless, in some countries, FSC/CFG are still considered a required document for medical device premarket submissions and post-market activities, including market license renewal and tenders. In many instances, authorities still require these certificates to be authenticated through the process of notarisation, apostille or consular legalisation, adding time and cost without a clear benefit regulatory decision-making and patient access to medical technologies.

Fragmented and inconsistent FSC/CFG requirements across the region create regulatory inefficiencies, duplicate documentation, and uncertainty in product registration pathways, particularly where certificates are unavailable. In some cases, these certificates are still required for tenders, even after market access has been granted in the form of a market authorisation license by its own authority, placing additional burden on manufacturers post-registration.

This position paper highlights that a valid market approval license from the country of origin or a recognised reference authority already demonstrates legal market placement, making additional FSC/CFG requirements redundant. It maps current practices across APAC, outlines key challenges faced by the industry, and provides risk-based recommendations to regulators. It explores opportunities to:

- Remove FSC/CFG requirements from premarket and renewal submissions where possible or alternatively accept evidence from the legal manufacturer's country or recognised reference authorities

- Simplify related certificate authentication processes, such as legalisation and notarisation

These actions aim to support a more efficient, transparent, and internationally aligned regulatory environment. All information presented in this paper reflects the most accurate and up-to-date data available at the time of publication.

TERMINOLOGY

Many of the terms used throughout this paper, such as “Certificate of Free Sale (CFS)”, “Free Sale Certificate (FSC)”, “Certificate of Foreign Government (CFG)”, "Legal Manufacturer", or “Market Authorisation License”, do not have a globally standardised definition and may vary depending on the regulatory framework of each market. For the sake of clarity and consistency, APACMed has adopted definitions as referenced in the paper to guide this analysis. Readers are encouraged to refer to local regulations when interpreting terms, as actual usage may differ in specific jurisdictions. This standardisation aims to support meaningful comparisons and focused policy dialogue.

Apostille
An Apostille is a legal certification that represents the legalisation, authentication of the signature, seal and position of the official who has executed, issued or certified a copy of a document. An Apostille will be recognised as valid in all countries that are part of the 1961 Hague Convention.

Apostille Convention
The “Hague Apostille Convention”, formally known as the Convention of 5 October 1961 Abolishing the Requirement of Legalisation for Foreign Public Documents, was established to facilitate the international acceptance of public documents. Its central objective is to remove the necessity for diplomatic or consular legalisation among member states. Through this convention, a document originating in one member country may be certified with an apostille, enabling its legal recognition in another member country without additional authentication processes.[1]

Authentication
For the purpose of this paper, authentication for certificates and/or other documents refers to the process of verifying a document to confirm the signature, seal or stamp is legitimate as well as to validate the issuing authority. This can include a notarisation, apostille or legalisation.

Certificate to Foreign Government (CFG)
According to the US FDA a Certificate to Foreign Government (CFG) is a certificate for the export of medical devices that can be legally marketed in the United States (U.S.) that are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2]

Country of Origin (COO)
COO refers to the country where the medical device is either (a) subjected to substantial transformation (i.e., a significant change in form, function, or character) or (b) where the legal manufacturer is established and holds responsibility for compliance with applicable regulatory requirements. The applicable definition depends on the regulatory or trade context.[3,4]

Free Sale Certificate (FSC) and Certificate of Free Sale (CFS)
A Certificate of Free Sale (CFS), also known as a Free Sale Certificate (FSC), is a document issued by a competent authority confirming that a specific medical device or product is legally marketed or freely sold in the country of origin. This certificate serves as evidence that the product complies with the regulatory requirements of the exporting country and is authorised for sale in its domestic market.[5] For the purpose of this document, we use the terms CFS and FSC interchangeably.

Legalisation
“Legalisation” means the formality by which the diplomatic or consular agents of the country in which a document is to be used certify the authenticity of the signature, the capacity in which the person signing the document has acted and, where appropriate, the identity of the seal or stamp which it bears.[6] Documents legalised in this way are valid for use only in the country represented by the certifying diplomatic or consular agent.

Legal Manufacturer (LM)
In accordance with the Medical Devices Regulation (EU) 2017/745, the legal manufacturer definition is: “A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark”.*

Market Authorisation or Approval license (MAL)
A formal approval granted by a regulatory authority for a medical device or an in-vitro-diagnostic device to be placed on the market, based on its compliance with regulatory standards for safety, performance, and quality. For the purpose of this document, we use the terms market authorisation licence, approval licence and MAL interchangeably.

Notarisation
Notarisation is the formal process of verifying the authenticity of documents and signatures through notarial acts. This function is performed by a notary public—an impartial official authorised by the government to execute legal formalities in order to deter fraud and instil confidence in transactions. Notarial acts encompass services such as acknowledgments, jurats, oaths, and copy certifications, each aimed at confirming the identity of the signer, their willingness to sign, and the document’s integrity. Such acts play a crucial role when documents are required for use in international contexts, in these instances, a notorised document may be further authenticated with an apostille certificate or through legalisation procedures.[7]

Physical manufacturer
In the Association of Southeast Asian Nations (ASEAN) Medical Device Directive, a physical manufacturer is defined, in relation to a medical device, as any person who performs the activity of manufacture.[8]

Reference Authority
The World Health Organisation (WHO) defines a reference regulatory authority as a national or regional authority or a trusted institution whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions.[9]

The list of recognised reference authorities may vary between jurisdictions. Readers are encouraged to refer to the official websites of the respective national regulatory authorities for the most up-to-date and market-specific information on which reference authorities are accepted.

* In many instances, the legal manufacturer of a medical device also serves as the COO and carries out manufacturing at the same location. However, there are cases where the legal manufacturer and the physical manufacturing site are situated in different countries. In this paper, the term "COO" refers specifically to the physical manufacturing site, and "country of COO" denotes the country in which that site is located.

The term "legal manufacturer" may imply that the entity must engage in the physical processing or manufacturing of the device. However, under both IMDRF framework (e.g., IMDRF/GRRP WG/N47FINAL:2018), the manufacturer is defined as the party responsible for the device, regardless of whether they conduct the manufacturing directly or via a third party. In other words, the manufacturer (or legal manufacturer) may not physically manufacture or refurbish the device at all, but is still the entity that places the device on the market under their name, holds the regulatory approvals, maintains the quality management system (e.g. ISO 13485), and assumes full responsibility for regulatory compliance, including post market surveillance, recalls, and field safety corrective actions.

3 REGULATORY LANDSCAPE IN APAC

This section presents a landscape of regulatory requirements across key APAC markets, drawing on current regulations and publicly available guidance documents. It aims to provide a comparative overview of the conditions under which FSC/CFG are required.

To support a more granular understanding of regulatory expectations, the landscape has been divided into three subsections:

1. New Registrations
2. Renewal Registrations
3. Other Requirements (e.g.,certificate authentication, hardcopy requirements)

Each subsection is mapped against a defined set of criteria, such as whether a technical dossier is required, whether approval or certification must come from the legal manufacturer or from a recognised reference authority, and whether certificate authentication or physical submission of documents is necessary. This structure allows us to identify areas of convergence and divergence across jurisdictions and supports the development of policy recommendations for more streamlined and harmonised approaches.

In several instances, manufacturers and distributors have reported differences between regulatory requirements and what is expected or accepted in practice. In such cases, the table reflects current regulations and publicly available guidance documents. These discrepancies will be further explored in Section 4 - the “Challenges” section of this paper.

This landscape reflects the situation as of the date of publication; however, it is encouraging to note that several APAC markets have already signalled changes in this direction through draft regulations and updated guidance documents that reduce or eliminate FSC requirements.

3.1 Mapping of FSC/CFG requirements across APAC for a new registration

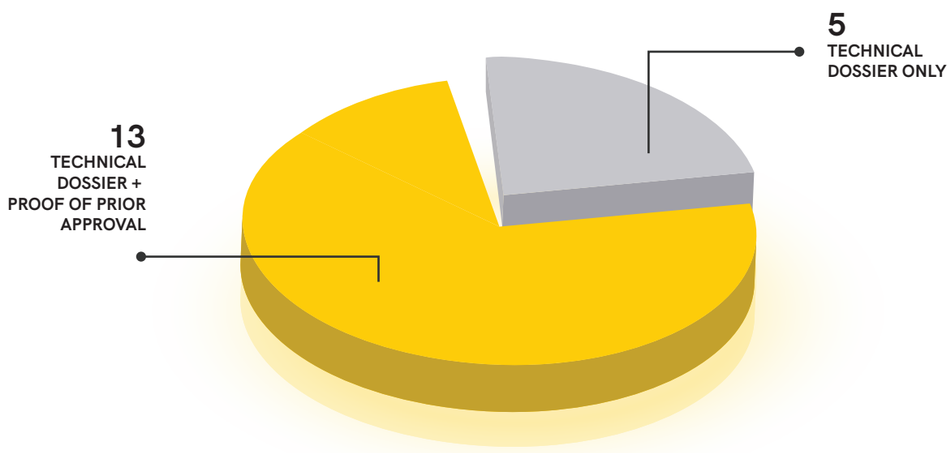
MARKET	REQUIRES A TECHNICAL DOSSIER	REQUIRES THE MARKET AUTHORISATION LICENSE (MAL)	REQUIRES THE FSC/CFG		
		From a Ref NRA, the country of LM, or the COO	From a Ref NRA	From the Country of LM	From the COO
AUSTRALIA	✓	✗	✗	✗	✗
BANGLADESH	✓	✓	✓	✗	✓
CAMBODIA	✓	✗	✗	✗	✓
CHINESE MAINLAND	✓	✓	✗	✗	✗
INDIA	✓	✓	✓ Either Ref NRA/ COO	✗	✓ Either Ref NRA/ COO
INDONESIA	✓	✓	✓ Either LM/COO/ Ref NRA	✓ Either LM/COO/ Ref NRA	✓ Either LM/COO/ Ref NRA
JAPAN	✓	✗	✗	✗	✗
LAOS	✓	✓	✗	✗	✗
MALAYSIA	✓	✗	✗	✗	✗
MYANMAR	✓	✗	✗	✓ Either LM/ COO	✓ Either LM/ COO
PAKISTAN	✓	✓	✗	✓	✗
PHILIPPINES	✓	✓	✗	✗	✗
SINGAPORE	✓	✗	✗	✗	✗
SOUTH KOREA	✓	✗	✗	✗	✗
SRI LANKA	✓	✓	✗	✗	✓
CHINESE TAIPEI	✓	✗	✗	✓ Either LM/ COO	✓ Either LM/ COO
THAILAND	✓	✓	✗	✗	✗
VIETNAM	✓	✓ Either MAL or FSC	✓ Either MAL or FSC	✗	✗

* Referenced National Regulatory Authority (Ref NRA), Country of Legal Manufacturer (LM), Country of Origin (COO)

** "COO" refers to the country recognised by the importing authority as the COO for FSC/CFG issuance, noting that the applicable definition and interpretation may differ between jurisdictions.

CHART 1

REGULATORY REQUIREMENTS IN APAC FOR A NEW REGISTRATION



Across APAC, authorities apply different premarket documentation requirements to approve medical devices. These comparisons show clear differences in how APAC markets approach premarket documentation. Some regulators rely only on their own technical assessments, while many combine dossier review with additional documents such as a MAL or FSC/CFG.

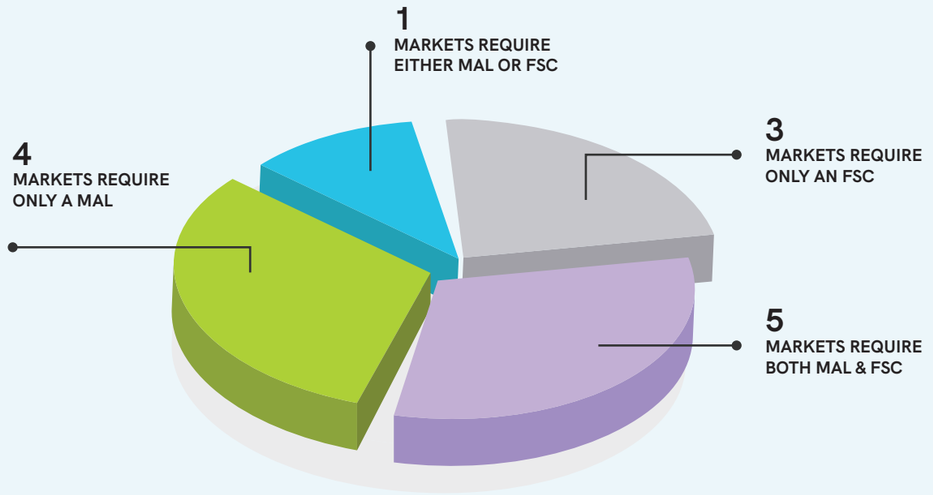
Chart 1 categorises markets into two groups based on their requirements:

- **Technical Dossier only:**
  Regulators perform their own assessment and do not require prior approval documents
  - In this group:Australia, Japan, Malaysia, Singapore, South Korea

- **Technical Dossier + Proof of Prior Approval:**
  Markets request both a local technical dossier and either a MAL or FSC/CFG from another authority
  - In this group: Bangladesh, Cambodia, Chinese mainland, India, Indonesia, Laos, Myanmar, Pakistan, Philippines, Sri Lanka, Chinese Taipei, Thailand, Vietnam

CHART 2

TYPES OF PROOF OF PRIOR APPROVAL REQUIRED IN APAC MARKETS FOR A NEW REGISTRATION



Among the APAC markets that require proof of prior approval, expectations vary between a MAL, an FSC/CFG, either, or both. Chart 2 groups these markets into four categories:

- **MAL only:**
  Regulators request a market authorisation license but do not require an FSC/CFG.
  - In this group: Chinese mainland, Laos, Philippines, Thailand

- **FSC/CFG only:**
  Regulators rely on an FSC/CFG, without requiring a MAL.
  - In this group: Cambodia, Myanmar, Chinese Taipei

- **Both MAL and FSC/CFG:**
  Regulators request submission of both documents for registration.
  - In this group: Bangladesh, India, Indonesia, Pakistan, Sri Lanka, with Balderdash and India requesting multiple FSC/CFG.

- **Either MAL or FSC/CFG:**
  Regulators request submission of either document for registration.
  - In this group: Vietnam

In markets where both a MAL and an FSC/CFG are requested, or multiple FSC/CFGs are requested, the documents ultimately provide overlapping evidence of prior approval. These variations translate into differing levels of administrative effort, which can in turn influence the pace at which patients gain access to medical technologies.

3.2
Mapping of FSC/CFG requirements across APAC for a renewal registration

This table includes only the APAC markets that require a renewal registration process and sets out their documentary expectations at renewal.

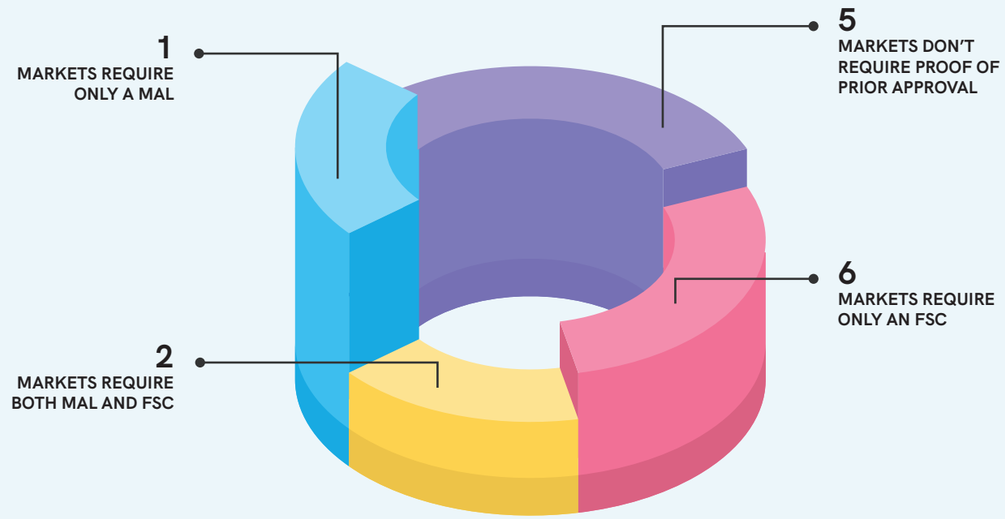
MARKET	REQUIRES THE MARKET AUTHORISATION LICENSE (MAL)	REQUIRES THE FSC/CFG		
	From a Ref NRA, the country of LM, or the COO	From a Ref NRA	From the Country of LM	From the COO
BANGLADESH	✓	✓	✗	✓
CAMBODIA	✗	✗	✗	✓
CHINESE MAINLAND	✗	✗	✗	✗
INDIA	✓	✓ Either Ref NRA/COO	✗	✓ Either Ref NRA/COO
INDONESIA	✗	✓ Either Ref NRA/ LM / COO	✓ Either Ref NRA/ LM / COO	✓ Either Ref NRA/ LM / COO
LAOS	✗	✗	✗	✗
MALAYSIA	✗	✗	✗	✗
MYANMAR	✗	✗	✓ Either LM/ COO	✓ Either LM/ COO
PAKISTAN	✗	✗	✓	✗
PHILIPPINES	✗	✗	✗	✗
SOUTH KOREA	✗	✗	✗	✗
SRI LANKA	✗	✗	✗	✓
CHINESE TAIPEI	✗	✗	✓ Either LM/ COO	✓ Either LM/ COO
THAILAND	✓	✗	✗	✗

* Referenced National Regulatory Authority (Ref NRA), Country of Legal Manufacturer (LM), Country of Origin (COO)

** "COO" refers to the country recognised by the importing authority as the COO for FSC/CFG issuance, noting that the applicable definition and interpretation may differ between jurisdictions.

CHART 3

TYPES OF PROOF OF PRIOR APPROVAL REQUIRED IN APAC MARKETS FOR A RENEWAL



Among the APAC markets that require documentation for renewal, expectations vary between a MAL, an FSC/CFG, none, or both. Chart 3 groups these markets into four categories:

- **MAL only:**
  Regulators request a market authorisation license without requiring an FSC/CFG.
  - In this group: Thailand

- **FSC/CFG only:**
  Regulators rely on a free sale certificate or equivalent, without requesting a MAL.
  - In this group: Cambodia, Indonesia, Myanmar, Pakistan, Sri Lanka, Chinese Taipei

- **Both MAL and FSC/CFG**:
  Regulators request submission of both documents for renewal.
  - In this group: Bangladesh, India

- **No proof of prior approval:**
  Markets that do not require a MAL or an FSC/CFG for renewal.
  - In this group: Chinese mainland, Laos, Malaysia, Philippines, South Korea

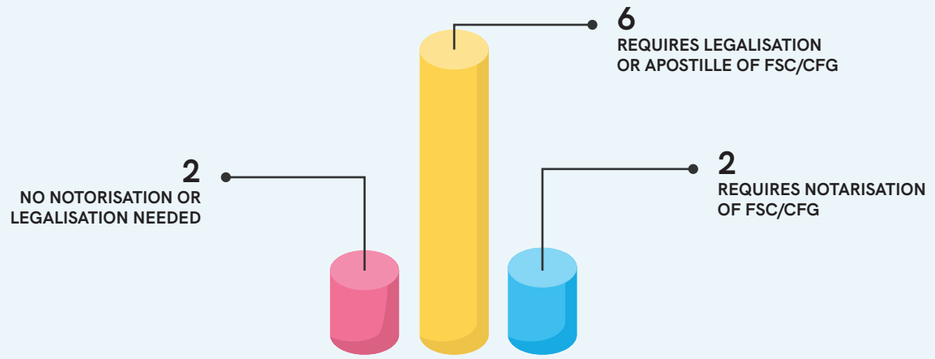
While most APAC markets do not require proof of prior approval at renewal, several still request a MAL, an FSC/CFG, or both. In these cases, the overlapping documentation adds administrative burden and can complicate timely renewals, creating uncertainty for manufacturers and potential delays in ensuring continuous patient access to existing medical technologies.

3.3
Additional FSC/CFG requirements across APAC

MARKET	REQUIRES NOTARISATION OF FSC/CFG	REQUIRES LEGALISATION OF FSC/CFG	MARKET IS PART OF THE HAGUE APOSTILLE CONVENTION
BANGLADESH	✗	✓	✓
CAMBODIA	✓	✗	✗
INDIA	✓	✗	✓
INDONESIA	✗	✗	✓
MYANMAR	✗	✗	✗
PAKISTAN	✗	✓	✗
SRI LANKA	✗	✓	✗
CHINESE TAIPEI	✗	✓	✗
VIETNAM	✗	✓	✗

CHART 4

NOTARISATION AND LEGALISATION OF FSC/CFG PRACTICES IN APAC



APAC markets differ not only in whether they require FSC/CFG, but also in the level of authentication applied to these documents. Chart 4 groups markets into three categories:

- **Notarisation required:**
  Two markets require FSC/CFG documents to be notarised by a public notary.
  - In this group: Cambodia and India

- **Legalisation or apostille required:**
  Six markets mandate either full legalisation through multiple authorities or an apostille under the Hague Convention.
  - In this group: Bangladesh, India, Pakistan, Sri Lanka, Chinese Taipei, Vietnam

- **No notorisation or legalisation needed:**
  Two markets require FSC/CFG in their original form without additional authentication.
  - In this group: Indonesia, Myanmar

Authentication practices for FSC/CFG vary widely across APAC. While only one market accepts certificates without additional steps, the majority still requires certificate authentication, which can be time-consuming and costly. These differing requirements create uneven administrative burdens and can slow patient access to approved technologies.

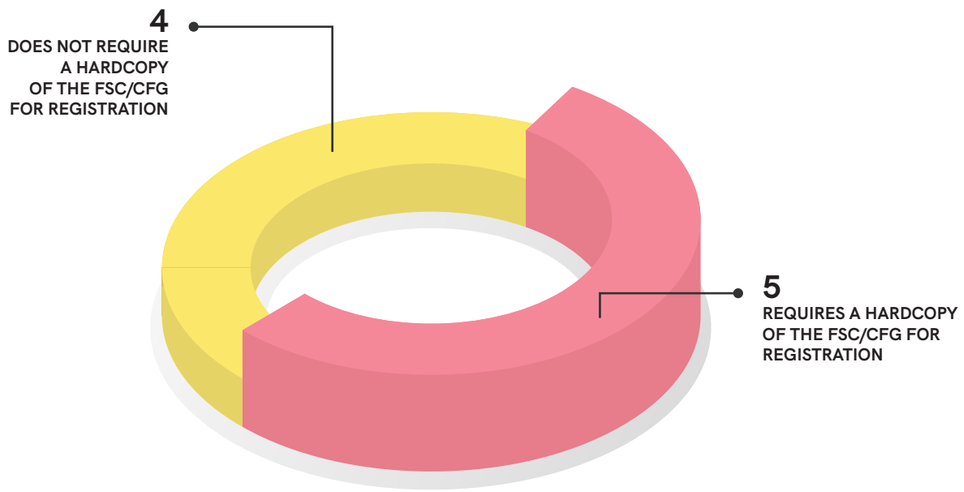
MARKET	REQUIRES A HARDCOPY OF THE FSC/CFG FOR REGISTRATION*
BANGLADESH	✓
CAMBODIA	✓
INDIA	✗
INDONESIA	✗
MYANMAR	✗
PAKISTAN	✗

MARKET	REQUIRES A HARDCOPY OF THE FSC/CFG FOR REGISTRATION*
SRI LANKA	✓
CHINESE TAIPEI	✓
VIETNAM	✓

*
This column reflects requirements for submitting a hardcopy of the FSC/CFG as part of the regulatory application process. It does not capture requirements related solely to internal record-keeping or archival purposes by local agents or applicants.

CHART 5

HARDCOPY FSC/CFG SUBMISSION REQUIREMENTS IN APAC



APAC markets also differ in whether they accept electronic submission of FSC/CFG or require physical hardcopies. Chart 5 groups markets into two categories:

- **Requires a hardcopy:**
  Four markets continue to mandate submission of original hardcopy certificates for registration.
  - In this group: Bangladesh, Cambodia, Sri Lanka, Chinese Taipei, Vietnam

- **Do not require a hardcopy:**
  Five markets accept FSC/CFG in electronic or scanned form without the need for physical submission.
  - In this group: India, Indonesia, Myanmar, Pakistan

Five APAC markets no longer require hardcopy FSC/CFG for registration, reflecting a shift toward digital acceptance. However, in other markets, reliance on hardcopies continues to add time, cost, and logistical hurdles for manufacturers. These requirements can slow down submission processes and reduce efficiency, particularly when electronic versions are already available and verifiable.

CHALLENGES AND GAPS

1. Redundant proofs of prior approval delay market access

In several markets, manufacturers are required to submit both a MAL and an FSC/CFG from a reference market or country of origin, even though both documents aim to demonstrate that a product is already approved, authorised, and marketed elsewhere. This duplication increases administrative burden and prolongs registration timelines without providing additional assurance of safety or effectiveness.

Where a device already holds a valid MAL from a recognised reference authority, requesting an FSC/CFG typically involves separate procedures, fees, and authentication steps, which introduce avoidable delays. These delays may be further exacerbated by external factors such as government shutdowns or public health emergencies in jurisdictions responsible for issuing or authenticating documents. Such overlapping requirements create inefficiencies for both applicants and regulators, particularly in cases where the same authority issues both documents.

In some jurisdictions, even when manufacturers pursue abridged registration pathways based on prior approval or authorisation in a reference market, authorities continue to request supplementary documents such as FSC/CFG. This practice undermines the intended efficiency of reliance-based approaches and weakens their regulatory value.

Over time, jurisdictions with duplicative or unpredictable documentation requirements risk being deprioritised in global launch planning, as manufacturers increasingly favour markets with more streamlined and predictable regulatory pathways.

2. Inconsistent FSC/CFG requirements and COO definitions complicate compliance

Despite the widespread use of FSC/CFG in APAC, regulatory authorities apply differing interpretations, formatting expectations, and assessment criteria. A key area of divergence is the definition of COO, which may refer to the legal manufacturer, physical manufacturing site, or place of substantial transformation. These differences affect which authority is expected to issue the FSC/CFG and can result in uncertainty or rejection when submissions do not align with local interpretations.

Authorities also require varying levels of detail in FSC/CFGs, including manufacturer information, manufacturing sites, and product identifiers, with inconsistent acceptance of product families versus exact Stock Keeping Units (SKUs). In addition, FSC/CFGs may be declined due to formatting expectations that are not part of the issuing country's standard template.

For products manufactured solely for export, where no registration exists in the country of manufacture, companies may be unable to obtain an FSC, leading to rejected applications. Further challenges arise when authorities expect FSC/CFGs to remain valid beyond submission, including for post-market activities or tenders, even when valid at the time of submission.

This lack of alignment in FSC/CFG content, source, and validity creates compliance challenges that delay submissions, increase administrative burden and regulatory costs, and ultimately slow patient access to medical technologies without providing additional assurance of quality or safety.

3. Continued FSC/CFG requests after market authorisation undermine regulatory sovereignty

In several APAC markets, FSC/CFG continue to be requested even after a product has received a full local MAL, particularly during post-market procedures such as licence renewals, public tenders, site registrations, or sample imports. These requests imply that a product already reviewed and approved by the national regulatory authority must still be supported by foreign regulatory documentation, raising questions about the standing of local regulatory decisions.

In practice, hospitals and procurement bodies may require up-to-date FSC/CFGs as part of qualification criteria, regardless of national approval. This reliance on third-party documentation can undermine confidence in national regulatory systems and signal a lack of trust in their own decision-making processes. Once a national MAL has been granted, it should be recognised as the highest evidence of compliance with safety, quality, and performance requirements.

4. Authentication requirements, and limited digital acceptance delay access

Many APAC regulators continue to require hard-copy FSC/CFGs with notarisation, apostille, or legalisation, even when secure digital versions are available through official government platforms. Requirements for physical stamping, embassy endorsement, or cross-border coordination introduce avoidable delays, particularly when legal and manufacturing entities are located in different jurisdictions.

Digital FSC/CFGs are often rejected unless printed and authenticated, and hard copies may still be required for archiving even when electronic submissions are accepted. These paper-based authentication practices offer limited regulatory value and delay product availability, despite the availability of secure digital tools such as official verification portals, QR codes, and digital signatures.

5. Misalignment between regulations and practices create operational uncertainty

Although regulations and guidance documents define formal regulatory requirements, manufacturers and distributors often encounter additional requests in practice that go beyond what is explicitly stated. For example, some authorities request inclusion of MALs from marketed countries in executive summaries, despite this not being required in official documentation. Similarly, in certain markets, FSC/CFGs from the legal manufacturer's country may be requested even when not stipulated in regulations, or alternative proof of approval may be accepted based on informal expectations.

Such divergence between published requirements and day-to-day practice creates uncertainty for manufacturers operating across multiple markets and undermines regulatory predictability. Greater alignment between documented regulations and actual implementation would improve transparency, legal certainty, and confidence in regulatory processes.

5 MOVING BEYOND FSC/CFG: LEGAL AND POLICY CONSIDERATIONS

To support a balanced and objective analysis, APACMed invited an independent legal review of the historical rationale and current relevance of FSC/CFG in medical device regulation. The following section has been prepared by K&L Gates, a global law firm with expertise in health and life sciences regulation. Their analysis outlines how the original policy purposes of FSC/CFG have evolved over time and offers a legal perspective on why, in the context of mature regulatory systems, such documents may no longer be necessary when a valid Market Authorisation License (MAL) is already in place.*

The use of FSC/CFG for the importation of medical devices have historically been adopted by "developing nations" based on a number of key policy considerations intended to support safe and efficient supply of medical devices in countries with limited regulatory resources.

We set out below the key policies traditionally underpinning the adoption of FSC/CFG:

1. Minimising costs and administrative burden for regulators

FSC/CFG are unusual regulatory requirements as they result in a "reversal" of the regulatory burden, which places obligation on the exporting market to certify compliance and safety measures. This can, in theory, minimise the administrative burden and costs to be borne by the importing jurisdictions. This is typically raised as a key policy reason where the importing jurisdiction has historically had limited regulatory expertise and/or resources, such that a developing regulator can rely on the FSC/CFG rather than undertaking their own comprehensive (and costly) regulatory approvals process.

Please note that the content in this Part 5 is provided for knowledge and informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.

2. Safety of devices

The use of FSC/CFG were traditionally seen as a tool which could increase consumer protection and confidence that devices meet minimum quality standards (as manufacturers must comply with exporting jurisdictions safety and quality requirements). Historically, FSC/CFG were usually adopted by developing countries to ensure that goods meet the same standards as those which are required to be met by the developed country in which the product was manufactured.

3. Regulatory dumping

When looking at the history of FSC/CFG, many jurisdictions considered import limitations as a reaction to legitimate concerns that developing nations could be a "dumping" ground for products which were otherwise deemed unsuitable for sale in more developed markets. FSC/CFG where therefore used to limit the risk of "regulatory dumping" of products which would not be fit for sale in the place of manufacture, as it is an import condition that the products are fit for sale in the place of manufacture.

The historical context which gave rise to the widespread use of FSC/CFG on the above policy grounds bears little resemblance to the current comprehensive regulatory processes and procedures across Asia Pacific today. As a result, the use of FSC/CFG in the modern processes for approvals of medical devices no longer assist with these policy aims.

As regulatory bodies across Asia Pacific have become more robust and experienced, the role of approvals for MALs has essentially replaced any policy concerns with respect to quality and safety of medical devices.

As MAL processes now involve detailed review of manufacturing for safety and efficacy purposes, the provision of an FSC provides little to no further comfort or safety protections for regulators or consumers. Rather than reducing the regulatory burden, the use of FSC can therefore result in a duplication of information and increase administration and regulation. This results in increased costs for the import of products (particularly where economies of scale cannot be adopted because of a certification requirements) and material delays in the processing and approvals of applications for new products. It can also result in existing products experiencing delays in ongoing approvals and stock outs.

Further, in a global world (and with the advent of the internet) regulators now also have materially increased information gathering and sharing capacities, including:

- established protocols for information sharing across jurisdictions and post-market surveillance (including on safety and recalls)
- the ability to review and check foreign approvals online
- the ability to review online publications of key data through clinical trials, etc

These systems allow for comprehensive, real time and reliable information review, including up to date information from other regulators - such that the information contained in an FSC/CFG is of limited utility for assessing applications or the safety of devices.

As the Asia Pacific markets and device regulators have matured and regulatory processes across the globe have improved, the requirement for manufacturers to provide an FSC prior to allowing the submission of a technical dossier for approval no longer achieves the policy goal to facilitate a more efficient regulatory process, nor does it provide materially greater certainty for the safety and quality of devices in these markets.

6 RECENT DEVELOPMENTS AND CASE STUDIES

Over time, several regulatory authorities in Asia Pacific have evolved away from requiring FSC/CFG as part of premarket submissions. This section outlines three categories of market practices that illustrate such progress:

1. Never required FSC/CFG: Some regulators have never mandated these certificates and instead rely directly on a market authorisation licence from a recognised reference authority.
2. Moved away from requiring FSC/CFG: Authorities in this category previously required FSC/CFG but have since modernised their frameworks to streamline submissions.
3. Conditional use or hybrid models: Certain authorities still allow or request FSC/CFG in limited or conditional cases but accept equivalent documents or rely on technical dossiers and MAL from reference countries.

These examples demonstrate that credible alternatives exist and can serve as models for broader regulatory convergence.

6.1 Markets that never required FSC/CFG

Malaysia

Malaysia is an example of a market that does not rely on FSC/CFG. Prior to the Medical Device Act (Act 737), Malaysia did not require FSC/CFG under the voluntary registration scheme or for general importation, with safety and quality demonstrated through approvals from other regulated markets (such as CE mark or US FDA approvals) and ISO 13485 certification upon request by customs authorities or healthcare facilities. Under Act 737, medical devices are subject to mandatory registration with the Medical Device Authority (MDA) for importation and supply, in line with the WHO medical device life-cycle approach. At the pre-market stage, establishments submit evidence of conformity to the Essential Principles of Safety and Performance, Good Manufacturing Practices, and Good Distribution Practices, with reference authority approvals accepted as supporting documentation to aid conformity assessment under a reliance-based bridging review. As the MDA can perform technical reviews within its legal framework, neither a market authorisation licence nor an FSC/CFG from another market is required. FSC/CFG is not requested during on-market or post-market phases.

6.2
Markets that move away from requiring FSC/CFG

Thailand

According to the Medical Device Act B.E. 2551 (2008), as amended by the Medical Device Act (No. 2), B.E. 2562 (2019) effective 15 February 2021, the Thai FDA revised its medical-device framework, streamlining approval steps and issuing new change-notification guidance for both general MDs and IVDs. While the amendments do not explicitly reference the removal of "FSC," they modify documentation requirements and regulatory pathways, with certain documents no longer required for some device categories. Overall, the updates reflect a broader effort to simplify procedures and reduce documentation in Thailand's device regulatory system.

South Korea

Under the Medical Device Act and the IVD Medical Device Act, the South Korean Ministry of Food and Drug Safety (MFDS) requires the submission of technical documentation for certification and marketing authorisation approval of medical devices. In 2009, the MFDS formally abolished the requirement to submit an FSC/CFG as part of a regulatory improvement initiative, as stated in the official MFDS announcement letter issued alongside the revised regulation, with the aim of streamlining administrative and procedural requirements unrelated to medical device safety. This removal of market entry restrictions has since supported the development of a robust regulatory framework, simplified regulatory processes, reduced regulatory burden, and accelerated the market entry of emerging technologies.

6.3
Markets requesting FSC/CFG in limited or conditional cases

China

The National Medical Products Administration (NMPA) currently requests, at registration (for imported devices), a certificate or document issued by the applicant's country/region confirming the device is approved for market sale. In practice, NMPA accepts a MAL from either the legal manufacturer's country or the country of origin. Where the license does not include all necessary particulars, an FSC/CFG may be requested to supply the missing details (e.g., when a 510(k) letter does not indicate the manufacturing site). A 2024 draft of the "Medical Device Administrative Law" removes the request for this prior-approval certificate, under which both a market authorisation licence and an FSC/CFG would no longer be mandatory elements of China registration (if/when finalised).

7 APACMED RECOMMENDATIONS

Based on the regulatory requirements collected from various countries and recent good practices observed across the APAC region, we propose the following recommendations:

1. Eliminate FSC/CFG requirements when a valid MAL is already in place

For pre-market submissions: If a comprehensive technical review has been conducted by a recognised regulatory authority and a valid MAL has been granted, this should be accepted as sufficient proof that the MD/IVD is approved/authorised for marketing. Requiring an additional FSC/CFG at the time of initial registration, which serves primarily for export, is redundant and prolongs submission timelines without offering added assurance of safety or effectiveness.

For post-market activities: Once a product has received national MAL, the authority has already determined that it meets all safety, quality, and performance standards. Asking for FSC/CFG again during post-market activities, such as tenders, renewals, or sample imports, duplicates work already done and creates unnecessary delays or potential product discontinuity. The national MAL itself should serve as the definitive proof of approval throughout the product's lifecycle, based on initial approval and local market history.

2. Where an FSC/CFG is still required, allow acceptance from either the legal manufacturer's country or a recognised reference authority, not only from the country of origin (COO).

This approach enables flexibility while maintaining regulatory assurance and avoids unnecessary barriers caused by inconsistent definitions of COO. FSC/CFG issued by the Legal manufacturer's country or recognised reference authority should be accepted when they contain essential product and manufacturer information. This is particularly important when the device is manufactured solely for export and not marketed in the country of manufacture which is common in Original Equipment Manufacturer (OEM) arrangements. This approach better reflects global manufacturing practices and helps prevent unnecessary delays and duplicative requirements.

Regulators should also avoid rejecting FSC/CFGs based on minor formatting issues that stem from the issuing authority's standard template, if the core information is present and verifiable.

3. Eliminate notarisation and legalisation requirements

Authorities should remove certification authentication requirements, which often require embassy appointments, cross-border coordination, and physical document handling. These processes slow down market access without adding regulatory value. Importantly, eliminating these requirements does not compromise document reliability. FSC/CFGs are issued by trusted regulatory authorities and can be securely verified through official government websites, regulator-to-regulator communication, or other secure digital platforms. These verification methods are faster, more secure, and less error-prone than manual endorsements, making the process more efficient without reducing trust or transparency.

4. Promote acceptance of electronic MAL and FSC/CFGs issued through official government portals

Secure digital versions of FSC/CFG issued via official government platforms that offer the same level of authenticity and traceability as physical documents, with added benefits of speed, cost-efficiency, and reduced administrative burden. As governments worldwide move toward digitalisation, APAC regulators should fully recognise these documents without requiring them to be printed and authenticated. Accepting digital FSC/CFGs, and enabling electronic validation through QR codes, digital signatures, or secure portals, not only streamlines submissions but also strengthens document security, reduces processing times, and frees up resources for both regulators and applicants. Embracing digital formats is a key step toward regulatory modernisation and supports more resilient, efficient review systems.

5. Ensure FSC/CFG Requests Align with Published Regulations

To support predictability and reduce delays, regulatory authorities should ensure that actual practices reflect what is written in laws and official guidance. When documents like FSC/CFG or additional approval letters are requested without being clearly required in regulations, it creates uncertainty and increases administrative burden. Better alignment between documented requirements and day-to-day practices would improve transparency, help manufacturers plan submissions more effectively, and support timely access to medical technologies.

6. Explore reliance on existing approvals from trusted reference markets instead of requiring additional evaluation.

Regulatory authorities should consider relying more on existing approvals from trusted reference markets. If a device has already been thoroughly reviewed and approved by a well-established regulatory authority, this approval should serve as a strong foundation for local decision-making. By recognising these approvals, authorities can reduce duplication, speed up review timelines, and focus resources on higher-risk products or areas where local evaluation is truly needed. This approach supports global harmonisation efforts, promotes smarter use of regulatory capacity, and ultimately helps patients access safe and effective technologies more quickly. More information on regulatory reliance concepts can be found in the WHO's "Good Regulatory Reliance Practices" Document[§] and the IMDRF Regulatory Reliance Playbook.[†]

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https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/inspections/grelp-annex-10-trs-1033/trs1033_annex10-good-reliance-practices.pdf?sfvrsn=dd5502cb_17&download=true

†
https://www.imdrf.org/sites/default/files/2025-03/IMDRF%20Reliance%20playbook%20draft%20%28final%29.pdf

8 CONCLUSION AND NEXT STEPS

APACMed's research shows that requests for multiple proofs of prior approval (e.g., MAL together with FSC/CFG) serve overlapping purposes, and that additional burdensome authentication steps introduce administrative variability without improving legal certainty in modern systems. In today's mature regulatory environments, a valid market authorisation licence (from the legal manufacturer's country or a recognised reference authority) already meets the legal and safety aims that FSC/CFGs historically addressed. When additional certificates and paper-based attestations are streamlined and replaced with secure, verifiable evidence anchored in existing approvals, and when practice relies on existing market authorisations and electronic verification consistent with published requirements, pathways become more predictable and timelines shorten. This preserves regulatory assurance, improves efficiency, and ultimately translates into faster, sustained access for patients.

9 REFERENCES

1. HCCH
   Apostille Convention (overview & resources) - https://www.hcch.net/en/instruments/conventions/specialised-sections/apostille
2. U.S. FDA
   Types of Export Certificates for Medical Devices - https://www.fda.gov/medical-devices/exporting-medical-devices/types-export-certificates
3. U.S. CBP
   Marking of Country of Origin of U.S. Imports - https://www.cbp.gov/trade/rulings/informed-compliance-publications/marking-country-origin-us-imports
4. WTO
   Determination Of Country Of Origin Of Goods - https://www.wto.org/english/thewto_e/acc_e/kaz_e/wtacckaz50a1_leg_1.pdf
5. EU
   Regulation (EU) 2017/745 on Medical Devices (Article 60) - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
6. EU
   Regulation (EU) 2016/1191 on Public Documents - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1191
7. District of Columbia Code
   Uniform Law on Notarial Acts (ULONA, 2018) - https://code.dccouncil.gov/us/dc/council/laws/22-189?utm_source=chatgpt.com
8. ASEAN
   ASEAN Medical Device Directive (AMDD) - https://asean.org/wp-content/uploads/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf
9. WHO
   Good Reliance Practices (GRP) - https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/inspections/grelp-annex-10-trs-1033/trs1033_annex10-good-reliance-practices.pdf
10. MDA
    Regulation of Medical Devices in Malaysia - https://npra.gov.my/images/Announcement/2013/Slides-for-National-Regulatory-Conference2013/Plenary_12_-_Regulation_of_Medical_Devices_in_Malaysia_by_Mr._Zamane_Abd_Rahman.pdf
11. MDA
    How to Apply for Medical Device Registration under Medical Device Act 2012 (Third Edition) - https://portal.mda.gov.my/index.php/documents/guideline-documents/2896-how-to-apply-for-medical-device-registration-under-medical-device-act-2012-third-edition-pdf/file
12. MFDS
    Board Notice (revision abolishing FSC/CFG requirement) (Korean) - https://mfds.go.kr/brd/m_207/view.do?company_cd=&company_nm=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&page=133&seq=2779&srchFr=&srchTo=&srchTp=&srchWord=&utm

Bangladesh Ministry of Commerce — Gazette/Order (Medical Devices)
https://www.dpp.gov.bd/upload_file/gazettes/33970_33126.pdf

Cambodia, Department of Drugs and Food — Prakas No. 1258 (08-11-2012)
https://www.ddfcambodia.com/policies-a-laws/policies_laws_prakas/472-prakas-no-1258-date-08-11-2012-of-moh.html

China NMPA — Measures / Regulatory Notices (medical devices)
https://www.nmpa.gov.cn/xxgk/fgwj/flxzhfg/20250416172904188.html

India CDSCO — Medical Devices Rules
https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/

India CDSCO — Form MD-14 Checklist
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/14MD.pdf

Indonesia Ministry of Health — PMK No. 62/2017 (Medical Devices)
https://regalkes.kemkes.go.id/informasi_alkes/PMK_No_62.pdf

Indonesian Ministry of Health — Guideline for Evaluation of Medical Device and IVD (2020)
https://regalkes.kemkes.go.id/informasi_alkes/Indonesia%20Guideline%20for%20Evaluation%20of%20Medical%20Device%20and%20IVD%202020.pdf

Laos Food and Drug Department — Medical Device
http://www.fdd.gov.la/content_en.php?contID=30

Pakistan DRAP — Import and Export Guidelines (Medical Devices)
https://www.dra.gov.pk/wp-content/uploads/2022/04/Import-and-Export-guidelines-Final.pdf

Philippines FDA — Administrative Order 2018-002 (Medical Device Regulation)
https://www.hcch.net/en/states/hcch-members
https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2018-002.pdf

Philippines FDA — FDA Circular 2022-008 (Abridged Processing for ASEAN-approved devices)
https://www.fda.gov.ph/fda-circular-no-2022-008-abridged-processing-of-application-for-registration-of-medical-devices-approved-by-the-national-regulatory-authority-of-any-asean-member-country/#:~:text=This%20Circular%20aims%20to%20provide,under%20the%20AMDD%2DCSDT%20requirements.&text=This%20Circular%20shall%20apply%20to,are%20covered%20under%20AO%20No

Sri Lanka NMRA — Medical Devices Page
https://www.nmra.gov.lk/pages/medical-devices

Taiwan TFDA — Laws & Regulations (Medical Devices)
https://www.fda.gov.tw/ENG/lawContent.aspx?cid=5063&id=3354

Vietnam Ministry of Health — Decree 98/2021/ND-CP (Medical Devices)
https://imda.moh.gov.vn/documents/10182/0/E_1636511534239_98_2021_ND-CP_08112021-signed.pdf/6e96247f-e468-434c-a478-091e7cb159ef

(Unofficial English translation) — Decree 98/2021/ND-CP
https://asiaactual.com/wp-content/uploads/2021/11/Decree-98-2021.pdf

Arthur E. Appleton, Claudio Dordi, Certificates of Free Sale: Who is Being Protected from Whom?
Journal of International Economic Law, Volume 14, Issue 4, December 2011, Pages 719–763,

Davidson, A., Grace, A.J., Schwarz, E.W. et al.
The Value of the Certificate of Pharmaceutical Product in Registration of Medicinal Products.
Therapeutic Innovation Regulatory Science 36, 163–167 (2002).

Handbook of Medical Device Regulatory Affairs in Asia - Second Edition 2018,
Edited By Jack Wong, Raymond Tong

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The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**