



TAIWAN IVD REGULATORY MAP

A practical orientation for global RA teams entering Taiwan.

1 START HERE: WHAT IS THE PRODUCT IN TAIWAN?

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer / instrument, or software / other. Regulation is overseen by the Taiwan Food and Drug Administration (TFDA).



IVD reagent



Analyzer / instrument



Software / other

2 Choose the regulatory route

Taiwan classifies IVDs by risk. Class and category drive evidence, testing, and licensing expectations.

CLASS I



Low risk

Listing / simpler route

Lower risk IVDs with well-established performance and mature technology. Most are listed via a notification or listing pathway with annual declaration considerations.

CLASS II



Medium risk

License / market-approval route

Moderate risk IVDs that may impact diagnosis or patient management. Requires TFDA license with technical documentation, performance data, and quality system review.

CLASS III



High risk

License / market-approval route

High risk IVDs for critical decisions or serious conditions. Requires TFDA license with the highest level of evidence and comprehensive review.

3 Build the Taiwan market-access infrastructure



TFDA framework

Comply with the Medical Device Act and TFDA requirements for IVDs, including classification, licensing, QMS, registration, UDI, and post-market obligations.



Local license holder / medical device firm / importer

Partner with a Taiwan medical device license holder or importer to act as the responsible party for licensing, QMS, importation, and post-market obligations.



Chinese localization & submission language

All submissions, labels, and IFU must be in Traditional Chinese. Localize content to meet TFDA format and clinical practice expectations.



Product-specific testing / UDI / QMS readiness

Ensure product testing to Taiwan requirements, readiness for UDI registration, and a compliant QMS (ISO 13485) for TFDA review.

4 Build the evidence stack



Administrative

Application forms, legal documents, registration dossier, local authorization letters, and agreements.



Quality

QMS, design controls, manufacturing information, supplier management, and CAPA processes.



Analytical performance

Performance data, accuracy, precision, interference, LoD/LoQ, and stability studies.



Clinical / scientific

Clinical performance or scientific literature support where required by risk class and claims.



Labeling & IFU

Traditional Chinese labels and IFU with intended use, contraindications, warnings, symbols, and storage.



RA TRAP TO AVOID

Do not assume Class I, II, and III IVDs in Taiwan share the same obligations. Listing, license, and post-market expectations differ significantly by class and category. Confirm requirements early to avoid delays.



STRATEGIC INSIGHT

Correct classification, a capable local license holder, Chinese-ready labels/IFU, and UDI readiness are key drivers of a smooth route to Taiwan market access and long-term compliance.



TAIWAN IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III
Premarket pathway	Listing (exempt from license)	License	License
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ● ○
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High / comprehensive ● ● ● ● ○
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Extensive ● ● ● ● ●
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ● ○ ○	Very strong ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ● ○ ○	Strict / intensive ● ● ● ● ●

C Indicative route-based planning ranges

These are Hopestone planning estimates, not official review clocks. Actual duration depends on classification, dossier quality, testing complexity, and TFDA queries.



Listing (Class I) timelines are typically shorter and do not involve license review.



Class II and III license timelines vary with product complexity, testing needs, and TFDA technical review.

D Labeling & language essentials

Chinese-language support
Provide Chinese versions of key materials (labels, IFU, claims).

Product labeling
Chinese labels must include required product particulars per TFDA labeling principles.

Instructions for use
Chinese IFU required; clear, accurate, and consistent with intended use and performance.

Claims control
Claims must be truthful, verifiable, and supported by evidence and labeling.

Product identifier & documentation
UDI is expected for Class II and III devices per Taiwan's UDI implementation timeline and rules. Retain traceable records.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- TFDA Medical Devices Act
- Regulations Governing Issuance of Medical Device License
- Listing and Annual Declaration
- TFDA device-classification page
- TFDA registration-of-medical-devices page
- TFDA principles of preparing labels and instructions
- hopestonecapital.com



IMPORTANT: Product-specific requirements, standards, and current regulatory changes govern. Confirm current requirements before execution.