Guide to Verification & Validation (V&V) for Medical Devices – Thai FDA Requirements

This document provides manufacturers with a structured overview of the Verification and Validation (V&V) requirements for medical device registration in Thailand. It outlines the principles, documents, and tests required for each major area of the Summary of Verification and Validation (SVV). It also clarifies the standards accepted by the Thai FDA, including ISO/IEC, ASTM, EN, USP, JIS, GB/T, and TIS, with guidance on when and how each can be applied.

1. General SVV Principles and Documentation

- All test reports must include objectives, methodology, results, and conclusions, with clear identification of the device (name, code, lot).
- Tests must be performed on final product samples manufactured in the declared facility.
- The latest standard versions must be used; if older versions are cited, a GAP analysis must be attached.
- ISO/IEC 17025 accredited laboratories are preferred for critical tests.
- A documented rationale must be provided whenever a test is not performed.

2. Design Verification & Performance / Safety

Principles:

- Verify design meets functional, safety, and performance requirements.
- Provide worst-case justification when only one size/model is tested.
- Maintain traceability: specifications ↔ tests ↔ acceptance criteria.

Required Tests / Documents:

- Mechanical, physical, chemical performance tests (product-specific standards).
- Electrical safety & EMC: IEC 60601-1, IEC 60601-1-2.
- Environmental conditioning (temperature, humidity).
- Acceptance criteria and conclusions in reports.

3. Biocompatibility

Principles:

- Follow ISO 10993-1 for risk-based biological evaluation.
- Tests must be conducted on the final product or representative samples.
- Testing in ISO/IEC 17025 or GLP labs.

Required Tests / Documents:

- Cytotoxicity (ISO 10993-5).
- Sensitization & irritation (ISO 10993-10).
- Systemic toxicity (ISO 10993-11).
- Genotoxicity (ISO 10993-3).
- Hemocompatibility (ISO 10993-4).

- Implantation (ISO 10993-6, if applicable).
- Chemical characterization (ISO 10993-18, -17).
- Biological evaluation report.

4. Devices Containing Biological Material

Principles:

- Assess risks of infection and donor-related hazards.
- Provide full traceability and donor screening records.
- Validate inactivation and clearance processes.

Required Tests / Documents:

- Donor screening reports (PCR, serology).
- Viral clearance validation reports.
- Process validation reports for pathogen removal.
- Stability and shelf-life data for biological components.

5. Stability & Shelf-life

Principles:

- Demonstrate device maintains safety and performance for the claimed shelf-life.
- Real-time studies are preferred; accelerated testing acceptable if real-time is ongoing.

Required Tests / Documents:

- Real-time stability reports (3 batches).
- Accelerated stability (ASTM F1980).
- Chemical, physical, functional analysis at intervals.
- Final report with conclusions on shelf-life.

6. Packaging Validation

Principles:

- Validate packaging to maintain product integrity and sterility.
- Critical process requiring pre- and post-production validation.

Required Tests / Documents:

- ISO 11607-1/-2 compliance.
- Seal strength (ASTM F88).
- Bubble leak (ASTM F2096).
- Integrity and revalidation plan.
- Process validation report for sealing and packaging.

7. Transportation / Distribution

Principles:

- Simulate real-world transportation and distribution conditions.
- Use models appropriate for distribution cycles.

Required Tests / Documents:

- ASTM D4169 (distribution simulation).
- Drop test (ASTM D5276).
- Compression (ASTM D642).
- Vibration/shock (ASTM D999, ISTA).
- Post-transport inspection report.

8. Sterilization Validation

Principles:

- Validate sterilization process achieves required SAL.
- Provide protocols and reports for reproducibility.

Required Tests / Documents:

- EO sterilization (ISO 11135).
- Radiation sterilization (ISO 11137).
- Steam sterilization (ISO 17665).
- Biological and chemical indicator results.
- Certification of sterilization facility (ISO 13485/GMP).

9. Software Verification & Validation (incl. SaMD)

Principles:

- Follow IEC 62304 lifecycle processes.
- Integrate risk management and usability.
- Maintain traceability from requirements to tests.

Required Tests / Documents:

- Software lifecycle documentation (IEC 62304).
- Usability engineering (IEC 62366-1).
- Risk management file (ISO 14971).
- Unit, integration, system, regression tests.
- Validation reports and release documentation.

10. Cybersecurity

Principles:

- Evaluate and mitigate threats across device lifecycle.
- Provide post-market monitoring and incident response plan.

Required Tests / Documents:

- Cybersecurity risk assessment and traceability matrix.
- Security test reports (penetration, vulnerability scanning).
- Evidence of mitigation effectiveness.
- Post-market monitoring plan.

11. Artificial Intelligence / Machine Learning Components

Principles:

- Document dataset, performance metrics, and bias analysis.
- Provide retraining and monitoring plan.

Required Tests / Documents:

- Dataset description (source, size, distribution).
- Validation protocol and report with acceptance criteria.
- Clinical evaluation of AI model.
- Retraining and update plan.

12. Pre-clinical / Clinical Evidence

Principles:

- Provide pre-clinical and/or clinical evidence proportionate to risk.
- Follow Good Clinical Practice (GCP).

Required Tests / Documents:

- Pre-clinical study reports (in vitro, in vivo).
- Clinical evaluation report (CER).
- ISO 14155-compliant clinical investigation reports.

13. Risk Management & Traceability

Principles:

- Maintain updated Risk Management File (ISO 14971).
- Ensure full traceability from requirements to test evidence.

Required Tests / Documents:

- Risk Management File.
- Hazard analysis, FMEA, FTA.
- Traceability matrix.

14. Reporting & Acceptance Criteria

Principles:

- All reports must include objectives, methods, acceptance criteria, results, conclusions, and responsible signature.
- If incomplete, attach protocol and completion plan.

Required Tests / Documents:

- Complete test reports.
- Declarations of conformity.
- Certificates from accredited labs.
- GAP analyses when required.

Standards Guidance for Thai FDA

The Thai FDA generally prefers ISO/IEC standards for V&V activities. However, other standards such as ASTM, EN, USP, JIS, GB/T, and TIS may also be accepted if properly justified. Key considerations include:

- ISO/IEC: default and most straightforward for acceptance.
- ASTM/EN/USP/JIS: widely accepted for packaging, transportation, chemical, and mechanical testing.
- GB/T: accepted only with a GAP analysis demonstrating equivalence to ISO.
- TIS (Thai Industrial Standards): mandatory where national standards exist.

When using non-ISO standards, justification must be included, and reports should demonstrate equivalence with ISO/IEC requirements.

Disclaimer

This document is intended for informational purposes only and does not constitute an official regulatory guideline. While it provides general principles and references to commonly used standards, following these indications does not guarantee the successful approval, certification, or registration of a medical device with the Thai FDA or any other regulatory authority. Manufacturers remain fully responsible for verifying applicable requirements, consulting official regulations, and ensuring compliance with all relevant laws and standards.

Comparative Table of Standards Accepted by Thai FDA

Area of Test	Default ISO/IEC Standards	Other Acceptable Standards	Thai FDA / Practical Guidance
Biocompatibility	ISO 10993 series	USP <87>/<88>, ASTM F756, JIS equivalents, GB/T (with GAP analysis)	ISO preferred; others accepted if justified and tested in ISO 17025 labs.
Sterilization	ISO 11135 (EO), ISO 11137 (Radiation), ISO 17665 (Steam)	EN 556, USP sterilization chapters, ASTM E61x, national pharmacopeia	If not ISO, attach GAP analysis and justification.
Stability & Shelf-life	ISO 13485 (useful life guidance), ISO 14971 (risk mgmt)	ASTM F1980 (accelerated aging), ICH guidelines	Real-time preferred; accelerated accepted only if real-time ongoing.
Packaging Validation	ISO 11607-1 / ISO 11607-2	ASTM F88, ASTM F2096, EN 868 series, JIS Z 0238	ISO preferred; ASTM/EN/JIS accepted if equivalence is documented.
Transportation / Distribution	no single ISO; ASTM/ISTA commonly used	ASTM D4169, ASTM D5276, ASTM D642, ASTM D999, ISTA protocols	ASTM/ISTA profiles commonly used; distribution model must be documented.
Performance & Safety (Electrical/Mechanical)	ISO 14971 (risk), IEC 60601 series (electrical safety)	ASTM mechanical standards, EN equivalents, JIS, TIS	IEC/ISO preferred; EN/JIS/ASTM accepted with equivalence and traceability.
Software V&V (incl. SaMD)	IEC 62304, IEC 82304-1, IEC 62366-1	AAMI TIR45, FDA software guidance	IEC/ISO baseline; FDA/AAMI guidance accepted as supportive.

Cybersecurity	IEC 81001-1 (health IT software safety principles)	NIST SP 800-53, FDA cybersecurity guidance, ISO 27001 (as reference)	Thai FDA requires practical measures and a post-market monitoring plan.
Chemical / Material Characterization	ISO 10993-18, ISO 10993-17	ASTM methods, USP chapters, GB/T standards (with GAP analysis)	ISO preferred; GB/T accepted only with GAP analysis proving equivalence.
Design Verification & Performance	ISO 13485, ISO 14971	EN/ASTM/JIS product-specific standards, TIS	Worst-case selection and traceability must be documented.
Devices with Biological Materials	ISO 13485 + ISO 22442 (where applicable)	WHO guidance, pharmacopeial monographs	High scrutiny: donor screening and viral safety required.
AI / Machine Learning Components	ISO/IEC evolving standards (SaMD-related)	FDA/IMDRF guidance, EU MDCG documents	Rapidly evolving area: dataset description and bias analysis required.
Pre-clinical / Clinical Evidence	ISO 14155 (Good Clinical Practice)	Local GCP, regulator templates	Clinical evidence must be proportionate to device risk.
Risk Management & Traceability	ISO 14971, ISO 19218	FMEA, FTA, IEC 60812 concepts	Traceability matrix required for submission completeness.
Labeling & Regulatory Claims	ISO 15223-1 (symbols), ISO 20417 (labels)	Local labelling laws, FDA/TFDA guidance	Labels must be in Thai; health/medical claims are carefully scrutinized.