TÜRKIYE IVD REGULATORY MAP

A practical orientation for global RA teams entering Türkiye

START HERE: WHAT IS THE PRODUCT IN TÜRKIYE?

1 Confirm Turkish regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Türkiye uses an IVD regulation aligned closely with EU IVDR and local TITCK operational requirements.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A
Low risk

Self-declaration route

Lowest risk devices with well-established performance. Self-declaration by the manufacturer is sufficient for the lightest-route products.

CLASS B
Moderate risk

Conformity-assessment route

Moderate risk devices. Conformity assessment with external assessment where required.

CLASS C
High risk

Conformity-assessment route

High risk devices. Stronger conformity assessment and performance-evaluation expectations.

CLASS D
Highest risk

Conformity-assessment route

Highest risk devices. Highest evidence and control burden.

3 Build the Türkiye market-access infrastructure

CE / Turkish IVD regulation technical foundation
Design and document to EU IVDR-aligned requirements and prepare the Declaration of Conformity.

Turkish Authorized Representative / local registrant
Appoint a Turkish Authorized Representative and establish the legal registrant responsible for compliance.

ÜTS product & company registration
Register company and products in the Ürün Takip Sistemi (ÜTS). Ensure importer/distributor setup before placing on the market.

Turkish language readiness
Labeling, Instructions for Use (IFU), and market-facing documentation must be available in Turkish.

4 Build the evidence stack

Administrative foundation
Forms, technical file index, DoC, risk management, traceability, and post-market plan.

Quality / QMS evidence
QMS documentation, process validation, supplier controls, and CAPA records.

Analytical performance
Performance data, methods, study reports, accuracy, precision, and stability.

Clinical / scientific support
Clinical performance studies, literature support, and performance evaluation per risk class.

Labeling & IFU package
Turkish labeling, IFU, symbols, claims, UDI, and all required information.

RA TRAP TO AVOID

Do not assume EU CE marking alone completes Turkish market entry — local Turkish representation, ÜTS execution, and Turkish-language localization matter.

STRATEGIC INSIGHT

Türkiye is harmonized in technical framework but local in execution. Strong local-operational planning is essential to align with TITCK expectations.

Training overview — verify current product-specific requirements with TITCK and your Turkish Authorized Representative. Not legal advice.

TÜRKIYE IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

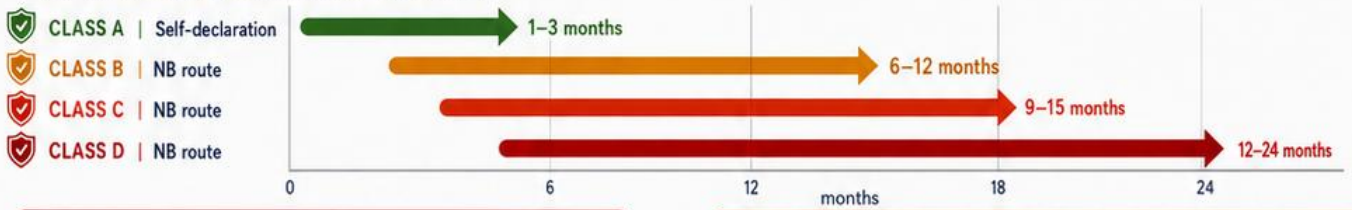
1. **Scope** — Define intended use, population and specimen type.
2. **Classify** — Class A / B / C / D per Turkish IVDR (TİTCK rules).
3. **Local agent setup** — Appoint a local authorized representative (importer) in Türkiye.
4. **Technical file & QMS** — Plan & complete technical documentation and QMS (ISO 13485) per IVDR.
5. **Conformity assessment** — Per route: eligible A self-declaration; B/C/D via NB.
6. **Submit** — Submit via ÜTS (Ürün Takip Sistemi) e-submission.
7. **Launch & maintain** — Post-market obligations: vigilance, changes, renewal & reporting.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Regulatory pathway	Self-declaration (eligible A)	NB route	NB route	NB route
Evidence intensity	Low ●○○○○	Moderate ●●○○○	High ●●●●○	Highest ●●●●○
Analytical performance	Basic ●○○○○	Moderate ●●○○○	High / comprehensive ●●●●○	Extensive ●●●●●
Clinical / scientific support	Not usually required ●○○○○	Limited ●●○○○	Extensive ●●●●○	Very extensive ●●●●●
Manufacturing / QMS readiness	Basic ●○○○○	Strong ●●●○○	Very strong ●●●●○	Excellent ●●●●●
Post-market control	Basic reporting ●○○○○	Enhanced ●●●○○	Strict / intensive ●●●●○	Very strict ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product type, testing needs, technical review, agency workload, and study requirements.



Eligible Class A self-declaration timelines are typically shorter but may vary by product category and local Center.

NB route timelines (Classes B–D) depend on review complexity, technical questions, and site inspections.

D Labeling & documentation essentials

Turkish-language labeling / IFU
All labeling and instructions for use (IFU) in Turkish.

Claims control
Claims must be truthful, verifiable and consistent with evidence.

Product-specific documentation
Technical file, performance evaluation, risk management, and PMS plan as per IVDR.

Traceability & UDI via ÜTS
Assign and maintain UDI and ensure traceability through ÜTS.

Vigilance & field actions
Report adverse events, FSCA/FSN, and CAPA via ÜTS.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Türkiye İlaç ve Tıbbi Cihaz Kurumu (TİTCK): titck.gov.tr
- Tıbbi Cihaz Yönetmeliği (AB) 2017/746 (IVDR) – Resmî Gazete No: 31741, 25 Mayıs 2022
- Ürün Takip Sistemi (ÜTS): utsuygulama.saglik.gov.tr
- Hopestone Capital & Consulting: hopestonecapital.com
- Template also reflects screening-level requirements from Hopestone's internal global device requirements workboook.

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