SAUDI ARABIA IVD REGULATORY MAP

A practical orientation for global RA teams entering Saudi Arabia

START HERE: WHAT IS THE PRODUCT IN SAUDI ARABIA?

1 Confirm Saudi regulatory identity

Confirm the intended use, specimen type, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and registration depend on the degree of risk to health and are determined under the SFDA regulatory framework and MDMA requirements.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A
Lower risk

Simplified route

Lowest risk devices with well-established safety and performance; streamlined technical review by SFDA/MDMA.

CLASS B
Moderate risk

Standard route

Moderate risk devices requiring stronger technical documentation and performance evidence; reviewed by SFDA/MDMA.

CLASS C
Higher risk

Extended route

Higher risk devices requiring deeper evidence and comprehensive evaluation by SFDA/MDMA.

CLASS D
Highest risk

Stringent route

Highest risk devices with the most stringent review and evidence requirements by SFDA/MDMA.

3 Build the Saudi market-access infrastructure

SFDA framework
Comply with Saudi Food & Drug Authority (SFDA) laws, regulations and guidance applicable to IVDs and supporting MDMA policies.

Saudi Authorized Representative
Appoint an SFDA-recognized Authorized Representative (AR) responsible for registration, compliance and post-market obligations.

Product registration & submission systems
Prepare for electronic submissions via SFDA systems (e.g., Wasfaty) and MDMA requirements. Maintain submission readiness.

Standards, QMS & importer readiness
Align with applicable standards (e.g., ISO 13485) and ensure importer/distributor partners are qualified and compliant.

4 Build the evidence stack

Administrative
Forms, technical file summary, certificates, product descriptors, intended use and company authorizations.

Quality
QMS, design controls, supplier management, risk management, CAPA and process validation.

Analytical performance
Performance data, accuracy, precision, reference materials, stability and interference.

Clinical / scientific support
Clinical evaluation, literature, published data and real-world evidence as applicable.

Labeling & IFU
Arabic labeling and IFU with intended use, indications, warnings and symbols per SFDA.

RA TRAP TO AVOID

Do not focus only on "How long does it take?" Begin with classification → choose route → secure Authorized Representative → prepare Arabic labeling → build evidence → ensure system readiness. The timeline is the result of those decisions.

STRATEGIC INSIGHT

Early Authorized Representative setup, mature evidence, Arabic-market readiness and submission planning are the biggest drivers of success with SFDA. Plan early and align to MDMA expectations.

SAUDI ARABIA IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

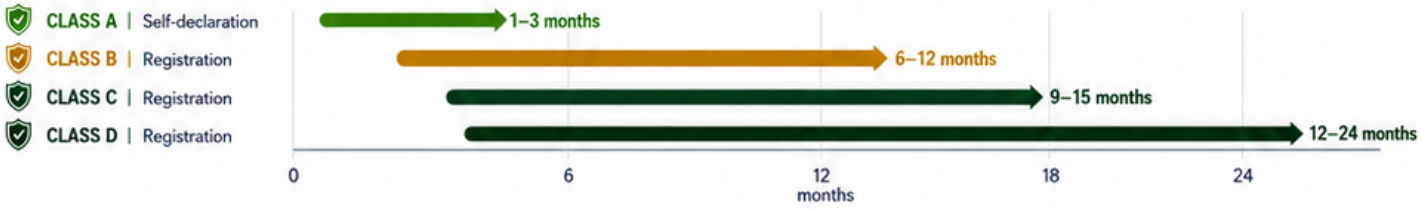
1. **Scope** — Define intended use, population and specimen type.
2. **Classify** — Class A–D per SFDA IVD classification rules.
3. **Authorized Representative setup** — Appoint Saudi AR (MAH) and establish local responsibilities.
4. **Technical file / standards** — Prepare documentation to GHTF/SFDA standards; ensure QMS readiness.
5. **Review by SFDA** — SFDA scientific and technical review.
6. **Decision & registration** — SFDA decision and issuance of MDMA/registration.
7. **Launch & maintain** — Post-market vigilance, field safety, changes, renewal & reporting.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Regulatory pathway	Self-declaration	SDoC + Registration	Registration	Registration
Evidence intensity	● ○ ○ ○ ○	● ● ○ ○ ○	● ● ● ○ ○	● ● ● ● ●
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Extensive ● ● ● ○ ○	Extensive ● ● ● ● ●
Quality system	Basic ● ○ ○ ○ ○	Strong ● ● ○ ○ ○	Very strong ● ● ● ○ ○	Robust ● ● ● ● ●
Post-market vigilance	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ○ ○ ○	Comprehensive ● ● ● ○ ○	Comprehensive + periodic PSUR ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on AR readiness, evidence maturity, SFDA review questions, and product risk.



These ranges reflect Hopestone experience across typical submissions. Simpler, lower-risk products trend shorter.

Actual timing depends on AR readiness, evidence maturity, SFDA review questions, and product risk.

D Labeling & language essentials

Arabic-language support
Provide Arabic versions of labels, IFU, and claims as required by SFDA.

Product labeling
Labels must include mandatory elements per SFDA guidance (in Arabic & English).

Instructions for use
IFU must be in Arabic. Follow SFDA template and content requirements.

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

Product identifier & documentation
Use SFDA product registration code (MDMA) and retain traceable records.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- SFDA Medical Devices Framework (MD-FR-01): https://www.sfda.gov.sa/en/md-framework
- SFDA IVD Classification Guidance: https://www.sfda.gov.sa/en/ivd-classification
- SFDA e-Submission (Ghad) Guidance: https://www.sfda.gov.sa/en/ghad
- SFDA Guidance for Medical Devices: https://www.sfda.gov.sa/en/guidance
- Template also reflects Hopestone-level requirements from Hopestone's internal global device requirements workbook.

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

