



SAUDI ARABIA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Saudi Arabia

START HERE: WHAT IS THE PRODUCT IN SAUDI ARABIA? ▶

1 Confirm the SFDA regulatory identity

Determine whether the product is a medical device under SFDA rules, identify intended use and claims, and classify the device using SFDA classification rules. The manufacturer classifies using the highest applicable risk rule.



General device



Software / connected



Sterile / implant / active

2 Choose the Saudi route

CLASS A



Lower risk

Lighter review path

Lower-risk devices still need SFDA-compliant classification and authorization.

CLASS B



Moderate risk

More evidence required

Technical and labeling scrutiny increase.

CLASS C



High risk

Heavy review

Clinical and product-specific evidence deepen.

CLASS D



Highest risk

Most demanding path

Highest-risk devices face the strongest premarket burden.

3 Build the Saudi market-access infrastructure



Local representative

Set up the manufacturer's authorized representative / liaison arrangements.



MDEL

Establishments such as importers, distributors, and ARs need medical-device establishment licensing.



MDMA

Plan the Medical Devices Marketing Authorization submission for products to be marketed in the Kingdom.



MDNR + UDI

Build national-registry, listing, and SAUDI-DI / UDI readiness.

4 Build the evidence stack



Administrative
classification
rationale, establishment
details, route strategy.



Quality / QMS
Supplier and manufacturing
readiness.



Technical / V&V
Bench, software,
EMC, biocompatibility,
sterilization as
applicable.



Clinical /
performance
Clinical evaluation
and product-specific
evidence.



Labeling / UDI
Labeling file, UDI
readiness, and
localization strategy.



RA TRAP TO AVOID

Do not assume other markets' approvals alone make a product ready for Saudi launch.



STRATEGIC INSIGHT

Saudi execution succeeds when establishment licensing, MDMA, UDI, and import readiness move in parallel.



SAUDI ARABIA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to launch — where the decision points and real-world friction sit

A Program flow

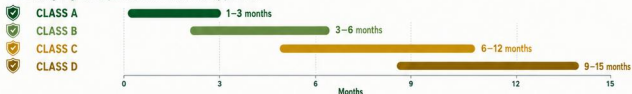


B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Exempt / lowest ● ● ● ● ●	Low ● ● ● ● ●	Moderate ● ● ● ● ●	Highest ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical / performance burden	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Planning ranges are Hopestone estimates, not authority promises.



Exempt (Class A) devices may follow a notification pathway, but must still meet all applicable requirements.



Actual timelines vary by product, evidence, dossier quality, SFDA questions, and workload.

D Labeling & launch essentials



E Country-specific decision points



Confirm product-specific requirements before execution.