MDS–G30

SFDA Reliance Approach for Medical Device

Version Number: 1.0
Version Date: 9/9/2026

MDS-G-030-V1/260909

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Introduction

The Saudi Food and Drug Authority (SFDA) is committed to ensuring the safety, quality, and effectiveness of medical devices in the Kingdom of Saudi Arabia, and that includes the promotion of rapid access healthcare technologies.

To optimize regulatory efficiency, SFDA utilizes a market access route through Regulatory Reliance. This approach allows manufacturers to use existing market authorizations and approvals from other jurisdictions to accelerate their SFDA Medical Device Marketing Authorization (MDMA) review process by relying on the conformity assessment already approved by a Recognized Regulatory Authority (RRA) to reduce the documentation requirements and shorten review timelines.

Scope

- This document provides a guidance for Manufacturers and Authorized Representatives (ARs) to obtain SFDA Medical Device Marketing Authorization (MDMA) certificate by utilizing authorizations and approvals from the following RRAs:

Country or Jurisdiction	Regulatory Authority
Australia	Therapeutic Goods Administration (TGA)
Canada	Health Canada
European Union (EU)	National competent authorities – European Economic Area (EEA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
United Kingdom (UK)	Medicines and Healthcare products Regulatory Agency (MHRA)
United States of America (USA)	U.S. Food and Drug Administration (FDA)

Note: The list of RRA may be updated periodically by the SFDA to include additional jurisdictions, including those of the IMDRF Management Committee (MC) members.

- This document also outlines SFDA's reliance on relevant post-market surveillance regulatory actions and information from RRAs to support its post-market regulatory activities and decision-making.

General Eligibility Criteria

To be eligible for the reliance pathway, a MDMA application must meet the following criteria:

- Hold a valid marketing authorization or approval from at least one RRA.
- Have identical technical aspects to the device authorized by the RRA including design, manufacturing process, and intended use.
- Comply with specific applicable requirements in Saudi Arabia. (e.g., Part 401 of Saudi Building Code (SBC) regarding electrical power voltage, frequency and colours of conductors' insulators; Labeling, IFU and user interface contents and language; Storage and transportation requirements related to temperature and humidity controls, etc.).

Quality Management System

The SFDA accepts Medical Device Single Audit Program (MDSAP) certificates and audit reports issued by MDSAP Auditing Organizations as evidence of conformity with Quality Management System (QMS) requirements. This reliance approach enables the SFDA to leverage the outcomes of audits conducted under the MDSAP framework, reducing duplication of regulatory assessment activities while maintaining confidence in the manufacturer's QMS.

Scope Exclusions

The following medical device types and market access routes are not eligible for the reliance pathway:

- Self-Registration Routes: Products granted market access through a manufacturer's self-registration or self-declaration process without an independent assessment by a regulatory authority or recognized third-party conformity assessment body.
- Equivalence to a Predicate Routes: Products granted market access primarily by demonstrating substantial equivalence to a predicate device.
- Custom-Made Medical Devices: Medical devices that meet the applicable criteria for custom-made devices as defined in the Implementing Regulation of Medical Devices Law.
- Products with Post-Market Safety Concerns: Products that are subject to significant post-market recalls, suspensions, withdrawals, or regulatory restrictions imposed by a RRA.
- Software as a Medical Device (SaMD) & AI-enabled Medical Device (AIeMD): SaMD and AIeMD may be excluded from the reliance pathway based on their intended use, level of risk, novelty, complexity, or other regulatory considerations as determined by the SFDA

Application Requirements

Applicants seeking to utilize the reliance pathway shall comply with the following requirements:

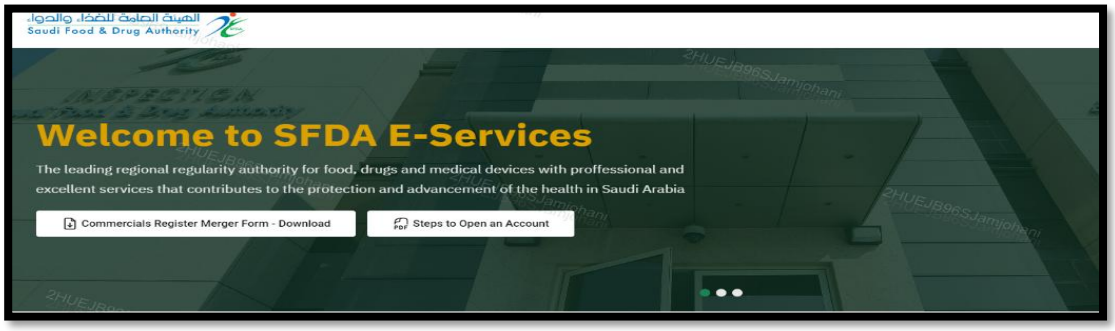
- Follow the SFDA classification rules to determine the proper risk class applicable for each medical device in accordance with the SFDA Guidance on Medical Devices Classification (MDS-G008).
- Where multiple medical devices are included within a single application, applicants shall comply with the SFDA Guidance on Bundling Criteria for Medical Devices within a Single MDMA Application (MDS – G028).
- Provide Evidence of a valid marketing authorization or approval issued by a RRA.
- Provide a rationale, as referred to in Annex (1), demonstrating of the suitability of choosing the reliance pathway.
- SFDA may require additional information based on the novelty, complexity, and risk profile of the medical device such as AIeMD, companion diagnostics and combination products.

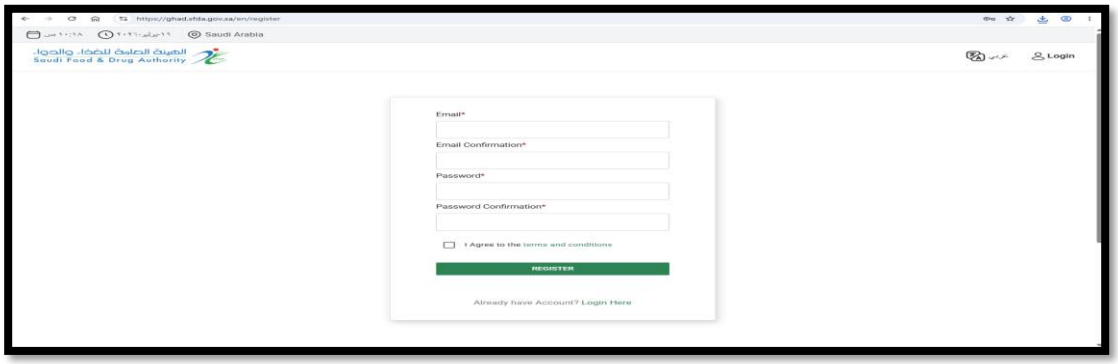
How to Apply

Eligible applicants can apply for the reliance route when submitting a MDMA application via the SFDA E-Services portal according to following steps:

Step1: Create an Account and Obtain an Establishment Number

Applicants who do not already have an account shall create one through the portal. Applicants with an existing SFDA account may proceed directly to Step 2.

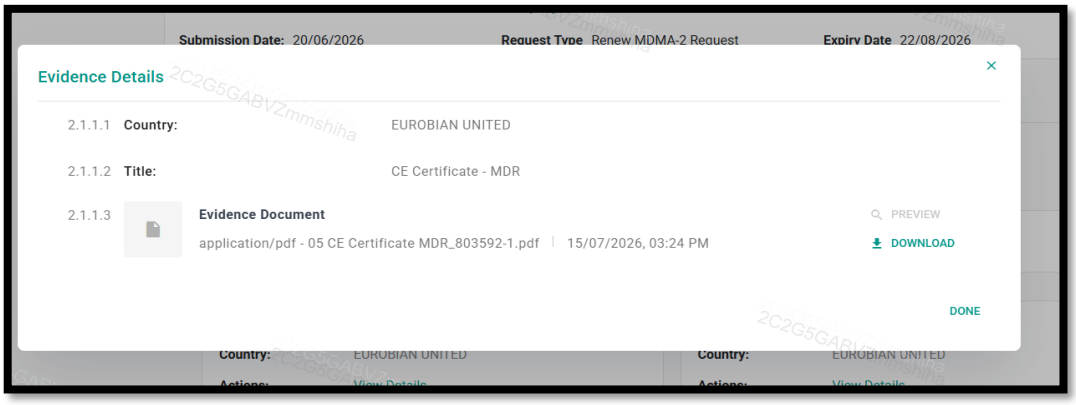




Step 2: Indicate Approval from a RRA

- In the “Overview” section of the MDMA application, the applicant shall answer “Yes” to the question in Subsection (2.1) to activate Subsection (2.1.1)

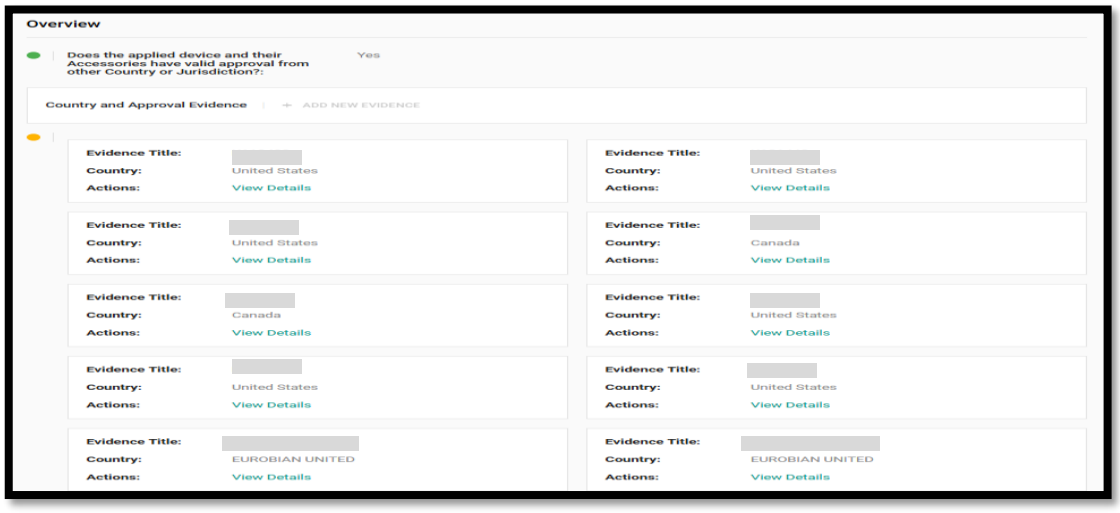
- Specify “Country” and “Title”, and upload Evidence Document for each obtained approval.

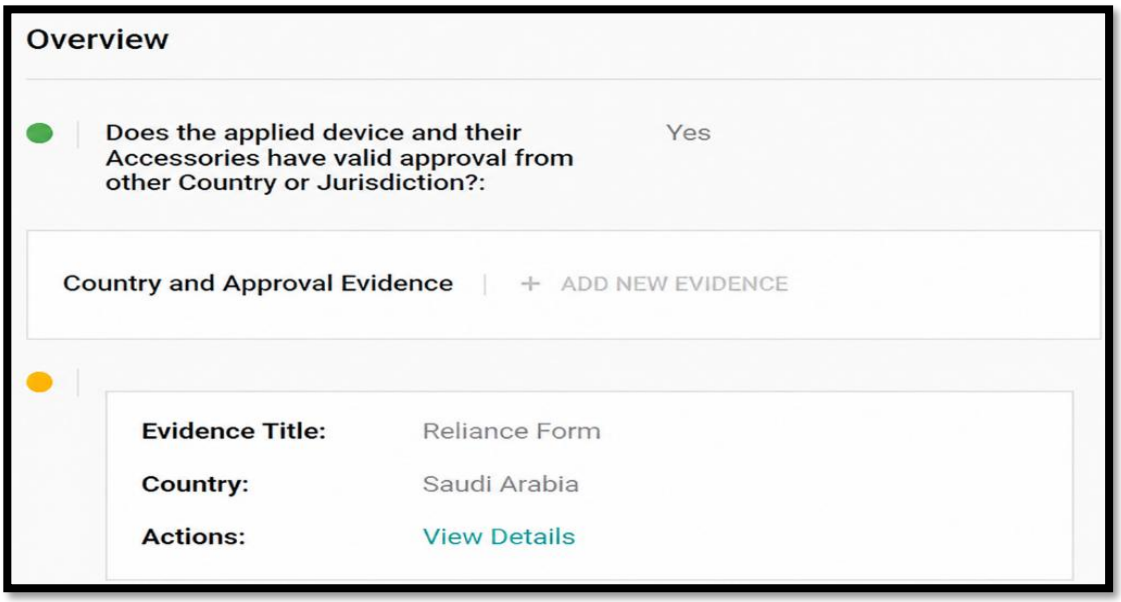


Step 3: Complete and Upload the ‘Reliance Form’

Applicant shall complete the “Reliance Form” provided in Annex (1), and upload it as part of the application.

The uploaded document shall be named "Reliance Form", and "Saudi Arabia" shall be selected as the applicable country.





Reliance Pathway Review Timeline

The standard review timeline for a MDMA application submitted through the reliance pathway is 35–60 working days, provided that the application is complete and all required documentation has been submitted.

Risk Class	Lead Time
Class A	35 – 60 Working Days
Class B	35 – 60 Working Days
Class C	35 – 60 Working Days
Class D	35 – 60 Working Days

Within the Reliance Pathway, review time may be reduced to 35 working days by relying on prior RRA approval instead of a full independent assessment, subject to eligibility and complete documentation.

Reliance in Post-Market Surveillance Activities

Reliance is an integral component of the SFDA's post-market surveillance approach for medical devices, supporting timely, consistent, and risk-based regulatory decision-making throughout the medical device lifecycle. Where appropriate, the SFDA considers relevant post-market surveillance regulatory decisions and information from RRAs. Such reliance helps avoid unnecessary duplication of regulatory activities, facilitates, early detection of emerging safety signals, and enables the SFDA to take proportionate and timely regulatory actions.

The SFDA applies reliance principles across several key post-market surveillance activities, including:

- **Definitions & Terminology:**

The SFDA adopts and utilizes internationally recognized IMDRF definitions and terminology relevant to post-market surveillance and vigilance activities, including terms related to adverse events, field safety corrective actions (FSCAs), and field safety notices (FSNs). This supports consistency in regulatory communication and facilitates the exchange and interpretation of safety information across jurisdictions.

- **Adverse Event Coding Systems:**

SFDA utilizes IMDRF adverse event terminology and coding systems to support standardized categorization of device-related problems, identification of potential causes, and analysis of adverse event trends. The use of internationally harmonized codes enhances data consistency and facilitates information exchange with other regulatory authorities.

- **Adverse event reporting requirements and timelines:**

Post-market reporting requirements and applicable timelines are established and implemented using a risk-based approach, taking into consideration the nature and severity of the event and the potential impact on patients, users, and public health.

- **Safety Alert Detection & Information Sharing:**

SFDA monitors safety information and regulatory actions published by recognized regulatory and competent authorities, including recalls, field safety corrective actions, and other relevant safety communications. Such information may be used as an important input for signal detection, prioritization of potential risks, and assessment of whether further regulatory action is warranted in the Saudi market.

Annexes

Annex (1) Reliance Form

[To be printed on the official letterhead of the Legal Manufacturer]

We [Name and Address of Medical Device Legal Manufacturer] hereby declare that the information and supporting documentation provided in this Reliance Form are true, complete, and accurate. We confirm that the regulatory approval(s) and supporting documentation submitted as part of this application are authentic and applicable to all listed medical devices included in this application. We acknowledge that the SFDA retains full decision-making authority regarding the granting of marketing authorization, and may request additional information or data during the review process, in accordance with the Medical Devices Law, its Implementing Regulation, and the published regulatory documents.

Information of Medical Device:

- Trade/Brand Name:
- Model Name/Number:
- Intended Purpose:
- SFDA Risk Class:

Recognized Regulatory Authority (RRA)
Country /Jurisdiction:

- ☐ Australia
- ☐ Canada
- ☐ European Union (EU)
- ☐ Japan
- ☐ United Kingdom (UK)
- ☐ United States of America (USA
- ☐ Others (please specify): ……

Rationale:

Provide justification for requesting review under the reliance pathway for this application. Include a brief summary of the device's worldwide regulatory status (e.g., approvals, clearances, or registrations in recognized jurisdictions), any supporting evidence demonstrating that reliance is appropriate for the device, and a confirmation that the device submitted to the SFDA is identical to the device authorized by the reference regulatory authority, including its intended purpose, design, specifications, manufacturing information, and labeling, where applicable.

Authorized Signatory

Name: Position:

Date: Signature:

Annex (2): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
Marketing Authorization (MDMA)	A document issued by the SFDA permitting the circulation of a medical device in the market.
Reliance	The act where by the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others
Custom-Made Medical Devices	a medical device that, at least, meets the following requirements: 1. Intended to a particular person (a patient or a healthcare professional); 2. Manufactured in accordance to a written request by an authorized professional specialist who, under his responsibility, gives specific design characteristics; and 3. It is intended to address the anatomo-physiological characteristics or pathological condition of the person for whom it is intended