SFDA Medical Device Registration Readiness Checklist

Saudi Arabia MDMA pre-submission checklist. Each line is something the SFDA assesses.

PRODUCT

- ☐ Medical device status confirmed
- ☐ Intended purpose defined in final wording
- ☐ Indications defined
- ☐ Contraindications defined
- ☐ Intended users identified
- ☐ Patient population identified
- ☐ Models and variants listed
- ☐ Accessories identified
- ☐ Software or AI content assessed

CLASSIFICATION

- ☐ Class determined under the SFDA rules
- ☐ All potentially applicable rules reviewed
- ☐ Rationale documented
- ☐ Formal classification request submitted where the position is unclear

REGULATORY STRUCTURE

- ☐ Legal manufacturer identified
- ☐ Authorized Representative appointed, license current
- ☐ Importer identified, license current
- ☐ Distributor identified
- ☐ Warehouse licensing confirmed
- ☐ Responsibilities allocated in writing

QUALITY

- ☐ QMS scope covers the declared sites and products
- ☐ ISO 13485 certificate current, expiry checked against target certificate validity
- ☐ Manufacturing site information available
- ☐ Supplier controls documented
- ☐ Risk management system operating

TECHNICAL DOCUMENTATION

- ☐ Device description
- ☐ Design information
- ☐ Manufacturing information
- ☐ Risk management file
- ☐ Verification data
- ☐ Validation data
- ☐ Performance testing
- ☐ Biological safety evaluation where applicable
- ☐ Electrical safety and electromagnetic compatibility (EMC) where applicable
- ☐ Sterilization and packaging validation where applicable
- ☐ Shelf life justification
- ☐ Software verification, validation and version scheme where applicable

EVIDENCE

- ☐ Clinical evaluation or performance evaluation
- ☐ Clinical investigation data where required
- ☐ Literature search documented and reproducible
- ☐ Every claim mapped to supporting evidence

REGULATORY HISTORY

- ☐ Declaration of conformity
- ☐ CE documentation where applicable
- ☐ FDA documentation where applicable
- ☐ Other national approvals
- ☐ Free sale certificate where applicable
- ☐ Regulatory actions, recalls or refusals disclosed

LABELING

- ☐ Device label
- ☐ Instructions for use
- ☐ Warnings and precautions
- ☐ Storage and handling information
- ☐ Arabic and English met for lay-person or self-test devices, including the user interface
- ☐ Arabic name as pronounced in English on the label where required
- ☐ Symbols per ISO 15223-1, non-standard symbols explained in the instructions for use
- ☐ SFDA logo absent from labeling
- ☐ Serious incident reporting statement names the SFDA
- ☐ Promotional material included in the file and claiming no more than the instructions for use, clinical evaluation and technical documentation support
- ☐ Mains design checked against 60 Hz, 230 or 400 V, SASO-2203 and Saudi Building Code part 401
- ☐ Saudi storage and transport conditions addressed in stability and packaging evidence

SUBMISSION

- ☐ Bundling assessed against MDS-G028
- ☐ Application assembled in GHAD
- ☐ Fees prepared
- ☐ Deficiency response plan and responsible people named

MARKET ENTRY AND POST-MARKET

- ☐ Import and shipment clearance requirements assessed
- ☐ Storage and transportation requirements assessed
- ☐ Distribution controls in place
- ☐ UDI and Saudi-DI plan complete
- ☐ Advertising review process defined
- ☐ Complaint procedure
- ☐ Vigilance procedure
- ☐ PMS procedure
- ☐ Field safety corrective action (FSCA) and recall procedure
- ☐ Change control procedure

Dossier Reuse Worksheet: CE, FDA and ISO 13485 Documents

Sort every document you already hold into reusable, needs work, or missing before fees are committed.

Document you hold	What it contributes	What still needs assessment	Status	Notes
CE marking under MDR	Conformity assessment, technical documentation structure	Mapping to SFDA essential principles, classification confirmed under SFDA rules	R / NW / M	
FDA clearance or approval	Regulatory and clinical evidence, review history	Intended purpose alignment, classification difference, evidence mapping	R / NW / M	
ISO 13485 certificate	QMS evidence	Scope of certification, sites covered, expiry date against certificate validity	R / NW / M	
Clinical studies	Clinical evidence	Relevance to the Saudi intended purpose and population	R / NW / M	
Clinical evaluation report	Structured clinical assessment	Claim-by-claim mapping to the Saudi indication wording	R / NW / M	
ISO 14971 risk file	Risk management evidence	Completeness, traceability to design outputs and labeling	R / NW / M	
Instructions for use	Labeling content	Saudi language requirements, symbol set, claim consistency	R / NW / M	
Other national registrations	Regulatory history	None of them substitute for the MDMA	R / NW / M	
Existing PMS system	Post-market framework	Saudi vigilance reporting obligations and the Authorized Representative's role in them	R / NW / M	
Existing distributor	Commercial channel	Whether they hold the correct establishment license, and who holds the registration	R / NW / M	

Status key

R = Reusable, submit essentially as is with administrative alignment only. NW = Needs work, content exists but requires supplementation, re-mapping to the Saudi intended purpose, or updating. M = Missing, a new document, test, assessment or evidence package is required.

Open questions for the gap assessment

Planning a Saudi submission?

Send us the device, the intended purpose and the dossier you already hold. EvySaif will confirm the classification, tell you what is reusable and what is missing, and give you a costed plan before you commit to the application.

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