



Saudi Arabia — RegIntel Gap Analysis

Full Tiles Coverage Assessment · SFDA Medical Device Regulations · Generated 09 Jul 2026

141

TOTAL TILES

48

APPROVED

83

NO DATA

7

REJECTED

3

UNDER REVIEW

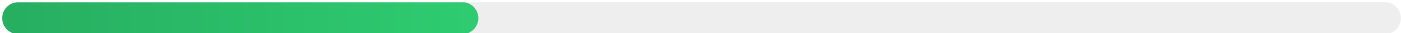
90

TOTAL GAPS

Executive Summary

This report presents the full gap analysis of RegDesk regulatory intelligence tiles for **Saudi Arabia (SFDA)** across all modules: Classification Rules, Obligations, Devices (9 device types), and Common Regulations.

Content Coverage: **34.0%** (48 of 141 tiles approved) Gap Rate: **63.8%** (90 tiles)



Classification Rules

Approved

Classification framework fully published

Obligations (5 tiles)

5/5

All obligation tiles approved

Common Regulations

8 gaps

out of 27 tiles — 70% coverage

Devices (9 types)

82 gaps

out of 108 tiles — 24% coverage

Electromagnetic Compat.

12/12 gaps

Highest priority — all tiles missing

In Vitro Diagnostic

7/12 OK

Best covered device type (58%)

1. Classification Rules & Obligations

Section	Sub Section	Released Status	Unreleased Status
Classification Rules	—	Approved	Approved
Obligations	Authorized Representative	Approved	Approved
Obligations	Distributor	Approved	Approved
Obligations	Importer	Approved	Approved
Obligations	Manufacturer	Approved	Approved
Obligations	Notified Body	Approved	Approved

2. Devices — Coverage by Device Type

Medical Device (2/12 approved · 17% coverage · 10 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	● Rejected	● Rejected
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	✗ No Data	✗ No Data
Labeling	✗ No Data	✗ No Data
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✓ Approved	✓ Approved

In Vitro Diagnostic (7/12 approved · 58% coverage · 5 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✗ No Data	✗ No Data
Clinical Trials	✓ Approved	✓ Approved
Importation	✗ No Data	✗ No Data
Unique Device Identification	✗ No Data	✗ No Data
Labeling	✓ Approved	✓ Approved
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✓ Approved	✓ Approved
Adverse Event Report	✓ Approved	✓ Approved
Renewal	✓ Approved	✓ Approved

Sub Section	Released Status	Unreleased Status
Materials Derived from Animal Origin	✓ Approved	✓ Approved

Combination Device (2/12 approved · 17% coverage · 10 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✗ No Data	✗ No Data
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	● Rejected	● Rejected
Labeling	✗ No Data	✗ No Data
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✓ Approved	✓ Approved

Radiation Emitting Device (4/12 approved · 33% coverage · 8 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	● Rejected	● Rejected
Clinical Trials	✗ No Data	✗ No Data
Importation	✓ Approved	✓ Approved
Unique Device Identification	✗ No Data	✗ No Data
Labeling	✓ Approved	✓ Approved
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✓ Approved	✓ Approved

Sub Section	Released Status	Unreleased Status
Post Market Surveillance	● Rejected	● Rejected
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data

Electromagnetic Compatibility Device (0/12 approved · 0% coverage · 12 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	● Rejected	● Rejected
Quality Management System	✗ No Data	✗ No Data
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	✗ No Data	✗ No Data
Labeling	✗ No Data	✗ No Data
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data

Wireless Device (3/12 approved · 25% coverage · 9 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✗ No Data	✗ No Data
Clinical Trials	✗ No Data	✗ No Data
Importation	✓ Approved	✓ Approved
Unique Device Identification	✗ No Data	✗ No Data

Sub Section	Released Status	Unreleased Status
Labeling	✓ Approved	✓ Approved
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	● Rejected	● Rejected
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data

Software Device (2/12 approved · 17% coverage · 10 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✗ No Data	✗ No Data
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	✓ Approved	✓ Approved
Labeling	✗ No Data	✗ No Data
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data

Implant Device (4/12 approved · 33% coverage · 8 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✗ No Data	✗ No Data

Sub Section	Released Status	Unreleased Status
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	✓ Approved	✓ Approved
Labeling	✓ Approved	✓ Approved
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✓ Approved	✓ Approved

AI Medical Device (2/12 approved · 17% coverage · 10 gaps)

Sub Section	Released Status	Unreleased Status
<i>Main tile</i>	✓ Approved	✓ Approved
Quality Management System	✓ Approved	✓ Approved
Clinical Trials	✗ No Data	✗ No Data
Importation	✗ No Data	✗ No Data
Unique Device Identification	✗ No Data	✗ No Data
Labeling	✗ No Data	✗ No Data
Advertisement and Promotion	✗ No Data	✗ No Data
Packaging	✗ No Data	✗ No Data
Post Market Surveillance	✗ No Data	✗ No Data
Adverse Event Report	✗ No Data	✗ No Data
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data

3. Common Regulations

16/27 tiles approved (59% coverage)

Sub Section	Released Status	Unreleased Status
Quality Management System	✓ Approved	✓ Approved
Clinical Trials	✓ Approved	✓ Approved
Importation	✓ Approved	✓ Approved
Unique Device Identification	✓ Approved	✓ Approved
Labeling	✓ Approved	✓ Approved
Advertisement and Promotion	✓ Approved	✓ Approved
Packaging	✓ Approved	✓ Approved
Post Market Surveillance	✓ Approved	✓ Approved
Adverse Event Report	✓ Approved	✓ Approved
Renewal	✗ No Data	✗ No Data
Materials Derived from Animal Origin	✗ No Data	✗ No Data
CE Marking	✓ Approved	✓ Approved
Cybersecurity	✓ Approved	✓ Approved
Recalls	✓ Approved	✓ Approved
Renewals	✓ Approved	✓ Approved
Establishment License	● Rejected	● Rejected
Timeline and Fees	✓ Approved	✓ Approved
e-Submission	✓ Approved	✓ Approved
Battery Requirements	✗ No Data	✗ No Data
Shelf-Life Requirements	✗ No Data	✗ No Data
REACH	✗ No Data	✗ No Data
ROHS	✗ No Data	✗ No Data
Change Control Requirements	✓ Approved	✓ Approved
Over-The Counter (OTC) Requirements	↻ Under Review	↻ Under Review
Export Certificates	✗ No Data	✗ No Data
Transportation and Storage	↻ Under Review	↻ Under Review
Waste Management	↻ Under Review	↻ Under Review

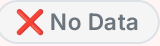
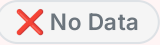
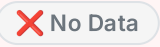
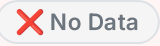
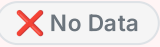
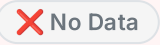
4. Gap Summary — Priority Tiles

Tiles with **No Data** or **Rejected** status — requiring immediate content population.

#	Section	Device Type / Sub Section	Tile	Status
1	Devices	Medical Device	Quality Management System	Rejected
2	Devices	Combination Device	Unique Device Identification	Rejected
3	Devices	Radiation Emitting Device	Quality Management System	Rejected
4	Devices	Radiation Emitting Device	Post Market Surveillance	Rejected
5	Devices	Electromagnetic Compatibility Device	Main tile	Rejected
6	Devices	Wireless Device	Post Market Surveillance	Rejected
7	Common Regulations	Establishment License	—	Rejected
8	Devices	Medical Device	Clinical Trials	No Data
9	Devices	Medical Device	Importation	No Data
10	Devices	Medical Device	Unique Device Identification	No Data
11	Devices	Medical Device	Labeling	No Data
12	Devices	Medical Device	Advertisement and Promotion	No Data
13	Devices	Medical Device	Packaging	No Data
14	Devices	Medical Device	Post Market Surveillance	No Data
15	Devices	Medical Device	Adverse Event Report	No Data
16	Devices	Medical Device	Renewal	No Data
17	Devices	In Vitro Diagnostic	Quality Management System	No Data
18	Devices	In Vitro Diagnostic	Importation	No Data
19	Devices	In Vitro Diagnostic	Unique Device Identification	No Data
20	Devices	In Vitro Diagnostic	Advertisement and Promotion	No Data
21	Devices	In Vitro Diagnostic	Packaging	No Data
22	Devices	Combination Device	Quality Management System	No Data
23	Devices	Combination Device	Clinical Trials	No Data
24	Devices	Combination Device	Importation	No Data
25	Devices	Combination Device	Labeling	No Data
26	Devices	Combination Device	Advertisement and Promotion	No Data
27	Devices	Combination Device	Packaging	No Data
28	Devices	Combination Device	Post Market Surveillance	No Data
29	Devices	Combination Device	Adverse Event Report	No Data

#	Section	Device Type / Sub Section	Tile	Status
30	Devices	Combination Device	Renewal	 No Data
31	Devices	Radiation Emitting Device	Clinical Trials	 No Data
32	Devices	Radiation Emitting Device	Unique Device Identification	 No Data
33	Devices	Radiation Emitting Device	Advertisement and Promotion	 No Data
34	Devices	Radiation Emitting Device	Adverse Event Report	 No Data
35	Devices	Radiation Emitting Device	Renewal	 No Data
36	Devices	Radiation Emitting Device	Materials Derived from Animal Origin	 No Data
37	Devices	Electromagnetic Compatibility Device	Quality Management System	 No Data
38	Devices	Electromagnetic Compatibility Device	Clinical Trials	 No Data
39	Devices	Electromagnetic Compatibility Device	Importation	 No Data
40	Devices	Electromagnetic Compatibility Device	Unique Device Identification	 No Data
41	Devices	Electromagnetic Compatibility Device	Labeling	 No Data
42	Devices	Electromagnetic Compatibility Device	Advertisement and Promotion	 No Data
43	Devices	Electromagnetic Compatibility Device	Packaging	 No Data
44	Devices	Electromagnetic Compatibility Device	Post Market Surveillance	 No Data
45	Devices	Electromagnetic Compatibility Device	Adverse Event Report	 No Data
46	Devices	Electromagnetic Compatibility Device	Renewal	 No Data
47	Devices	Electromagnetic Compatibility Device	Materials Derived from Animal Origin	 No Data
48	Devices	Wireless Device	Quality Management System	 No Data
49	Devices	Wireless Device	Clinical Trials	 No Data
50	Devices	Wireless Device	Unique Device Identification	 No Data
51	Devices	Wireless Device	Advertisement and Promotion	 No Data
52	Devices	Wireless Device	Packaging	 No Data
53	Devices	Wireless Device	Adverse Event Report	 No Data
54	Devices	Wireless Device	Renewal	 No Data
55	Devices	Wireless Device	Materials Derived from Animal Origin	 No Data

#	Section	Device Type / Sub Section	Tile	Status
56	Devices	Software Device	Quality Management System	 No Data
57	Devices	Software Device	Clinical Trials	 No Data
58	Devices	Software Device	Importation	 No Data
59	Devices	Software Device	Labeling	 No Data
60	Devices	Software Device	Advertisement and Promotion	 No Data
61	Devices	Software Device	Packaging	 No Data
62	Devices	Software Device	Post Market Surveillance	 No Data
63	Devices	Software Device	Adverse Event Report	 No Data
64	Devices	Software Device	Renewal	 No Data
65	Devices	Software Device	Materials Derived from Animal Origin	 No Data
66	Devices	Implant Device	Quality Management System	 No Data
67	Devices	Implant Device	Clinical Trials	 No Data
68	Devices	Implant Device	Importation	 No Data
69	Devices	Implant Device	Advertisement and Promotion	 No Data
70	Devices	Implant Device	Packaging	 No Data
71	Devices	Implant Device	Post Market Surveillance	 No Data
72	Devices	Implant Device	Adverse Event Report	 No Data
73	Devices	Implant Device	Renewal	 No Data
74	Devices	AI Medical Device	Clinical Trials	 No Data
75	Devices	AI Medical Device	Importation	 No Data
76	Devices	AI Medical Device	Unique Device Identification	 No Data
77	Devices	AI Medical Device	Labeling	 No Data
78	Devices	AI Medical Device	Advertisement and Promotion	 No Data
79	Devices	AI Medical Device	Packaging	 No Data
80	Devices	AI Medical Device	Post Market Surveillance	 No Data
81	Devices	AI Medical Device	Adverse Event Report	 No Data
82	Devices	AI Medical Device	Renewal	 No Data
83	Devices	AI Medical Device	Materials Derived from Animal Origin	 No Data

#	Section	Device Type / Sub Section	Tile	Status
84	Common Regulations	Renewal	—	 No Data
85	Common Regulations	Materials Derived from Animal Origin	—	 No Data
86	Common Regulations	Battery Requirements	—	 No Data
87	Common Regulations	Shelf-Life Requirements	—	 No Data
88	Common Regulations	REACH	—	 No Data
89	Common Regulations	ROHS	—	 No Data
90	Common Regulations	Export Certificates	—	 No Data

