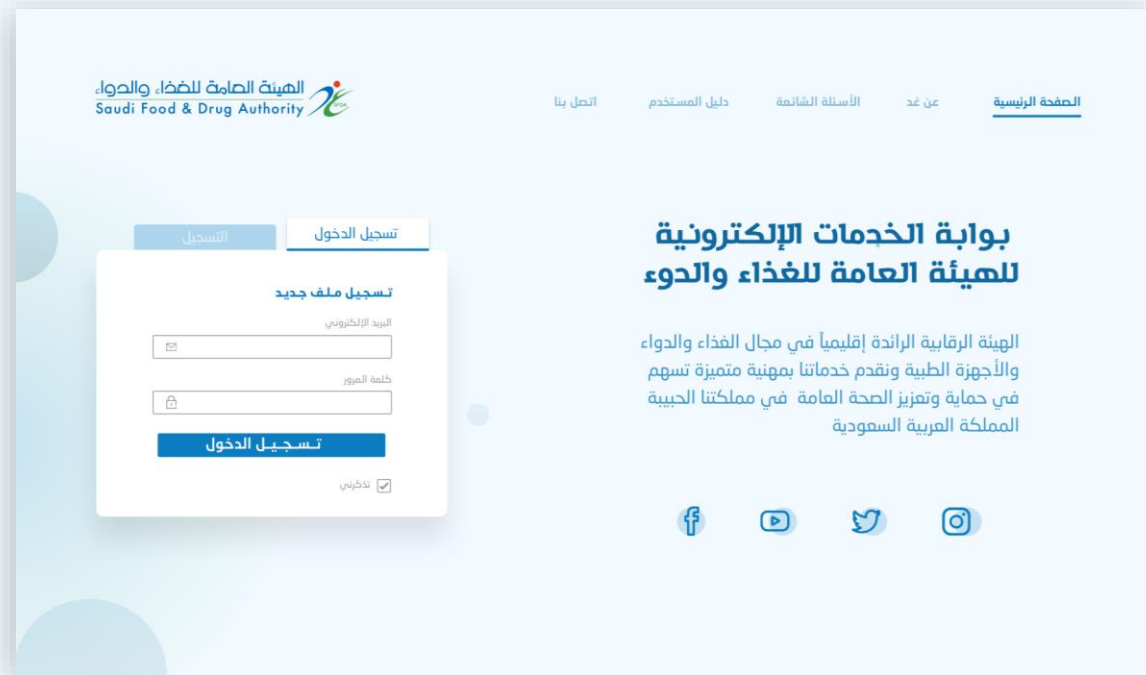


# User Guide for GHAD System

This Guide is for the User to Local Medical Devices License

# Login Page

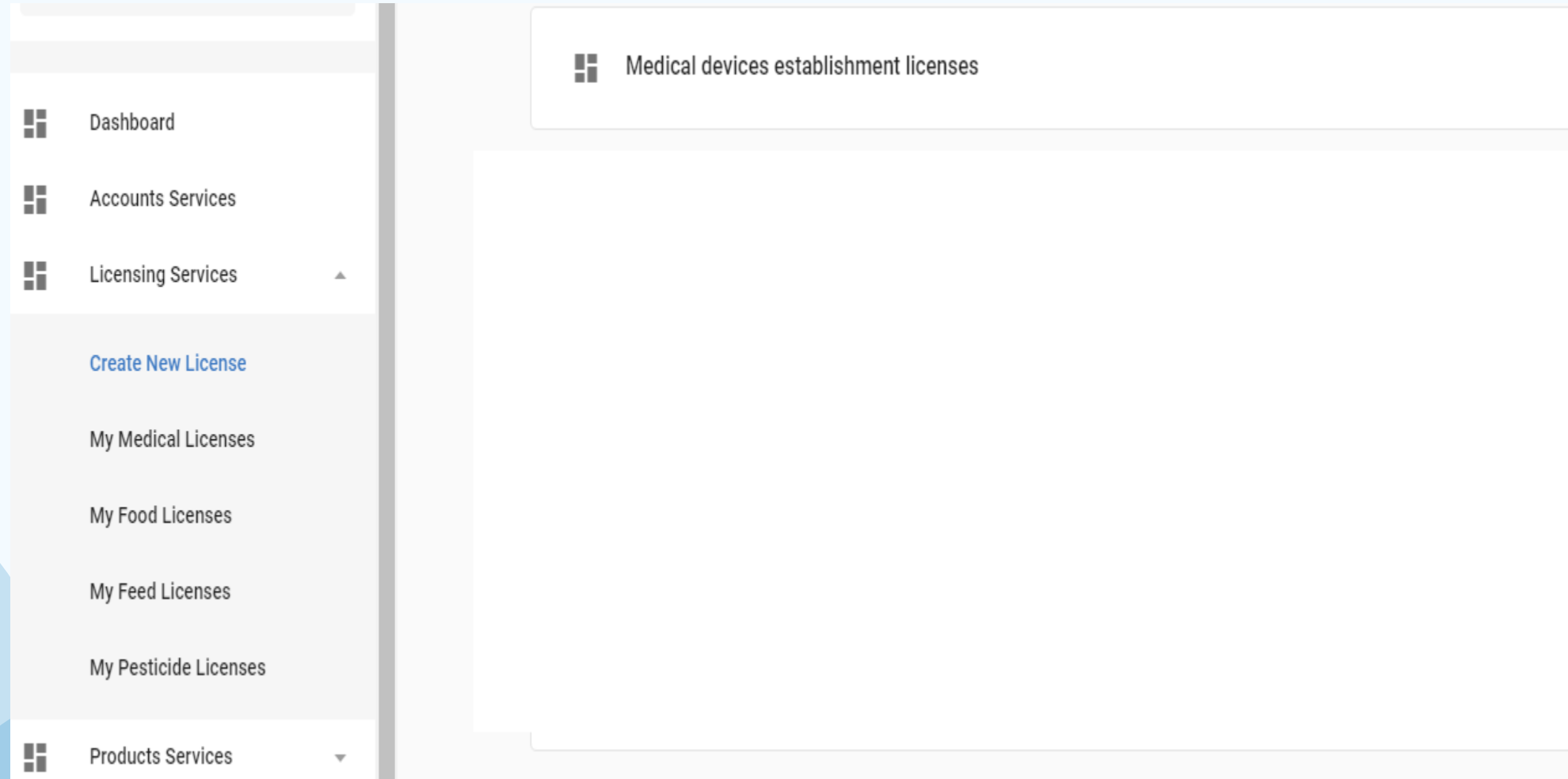
To enter, sign in or sign up



The screenshot shows the login page of the Saudi Food & Drug Authority. The page is in Arabic and features a navigation menu at the top with links for 'الرئيسية' (Home), 'عن غد' (About Us), 'الأسئلة الشائعة' (FAQ), 'دليل المستخدم' (User Guide), and 'اتصل بنا' (Contact Us). The main heading is 'بوابة الخدمات الإلكترونية للهيئة العامة للغذاء والدواء' (Electronic Services Portal for the Saudi Food & Drug Authority). Below the heading, there is a paragraph describing the authority's mission: 'الهيئة الرقابية الرائدة إقليمياً في مجال الغذاء والدواء والأجهزة الطبية ونقدم خدماتنا بمهنية متميزة تساهم في حماية وتعزيز الصحة العامة في مملكتنا الحبيبة المملكة العربية السعودية' (The leading regulatory authority in the region in the field of food and drugs and medical devices, and we provide our services with a high level of professionalism that contributes to the protection and promotion of public health in our beloved Kingdom of Saudi Arabia). There are also social media icons for Facebook, YouTube, Twitter, and Instagram. On the left side, there is a login form with two tabs: 'التسجيل' (Sign Up) and 'تسجيل الدخول' (Login). The 'تسجيل الدخول' tab is active, and the form contains fields for 'البريد الإلكتروني' (Email) and 'كلمة المرور' (Password), a 'تسجيل الدخول' button, and a 'تذكرني' (Remember me) checkbox.

# Local Medical Devices Process

## Type of license:



The screenshot displays the SFDA portal interface. On the left, a navigation menu is visible with the following items: Dashboard, Accounts Services, Licensing Services (with a right-pointing triangle), Create New License (highlighted in blue), My Medical Licenses, My Food Licenses, My Feed Licenses, My Pesticide Licenses, and Products Services (with a down-pointing triangle). The main content area on the right shows a header for 'Medical devices establishment licenses' with a grid icon to its left. Below this header, the main content area is currently blank.

## 1) Domain & Activity

Select the manufacturer in the main activity.

Account Name:

Domain\*  
Medical Device

Main Activity\*  
Manufacturer

## 2) Introduction

Read the terms, requirements,  
and fees.

(Electronic service to apply for a Local Manufacturer of Medical Devices/Products License)

Who must register?

An investor who wishes to obtain a license to manufacture medical devices/products for industrial activities (ISIC).

Conditions and Requirements:

1- Technical manager shall be met the following requirements: - A qualified, full-time (related technical specialty)

2- Quality manager shall be met the following requirements: - A qualified, full-time (related technical specialty)

3- Industrial license.

4- Manufacturer location shall be in a Manufacturer area and outside residential districts. Preferably, an industrial area away from pollution sources, sources that cause gases, vapors, flammables and exhausts that harm medical products.

5- The factory building should be designed according to the requirements of ISO 13485 standard in a way that preserves the product quality for medical devices and products approved by the authority.

6- The license of the municipality / government agency concerned with licensing the site.

7- Pay the license fee

8- Establish, Document, and apply the Quality Management System according to the Saudi Standard "Medical devices - Quality Management System - Regulatory Requirements (SFDA.MD/GSO ISO 13485:2016)

Financial Amount:

{expectedPayment} SAR

The license period is {licenseValidity} years

BACK

CONTINUE

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### 3) Manufacturer Information

Fill all the field and attach  
the required files.


Manufacture Name (In Arabic):

Manufacture Name (In English):

SFDA Account Number:


MODON License Number Or Municipal\*

MODON Contract or Municipal License\*

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

MODON Operational License

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Issuance Date\*



Expiration Date\*



Industrial Investment License No.\*

BACK

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#### 4) Manufacturer Activities

Select the Manufacturer Activities and the level of risk of medical devices.

##### Manufacturer Activities\*

- |                                      |                                    |
|--------------------------------------|------------------------------------|
| <input type="checkbox"/> Assembly    | <input type="checkbox"/> Design    |
| <input type="checkbox"/> Manufacture | <input type="checkbox"/> Packaging |
| <input type="checkbox"/> Renovation  | <input type="checkbox"/> Wrapping  |

##### The level of risk of medical devices and products to be manufactured\*

- |  |   |
|--|---|
| <input type="checkbox"/> Low Risk (A)            | <input type="checkbox"/> Low to Medium Risk (B) |
| <input type="checkbox"/> Medium to High Risk (C) | <input type="checkbox"/> High Risk (D)          |

Production Lines\*

BACK

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## 5) Device Categories

Select one or more device categories.

Select one or more device categories\*

 SELECT ALL

- |   |  |
|---|--|
| <input type="checkbox"/> Active Implantable Devices                     | <input type="checkbox"/> Anaesthetic and Respiratory Devices |
| <input type="checkbox"/> Assistive Products for Persons with Disability | <input type="checkbox"/> Biologically Derived Devices        |
| <input type="checkbox"/> Complementary Therapy Devices                  | <input type="checkbox"/> Dental Devices                      |
| <input type="checkbox"/> Diagnostic and Therapeutic Radiation Devices   | <input type="checkbox"/> Electro Mechanical Medical Devices  |
| <input type="checkbox"/> Healthcare Facility Products and Adaptations   | <input type="checkbox"/> Hospital Hardware                   |
| <input type="checkbox"/> In Vitro Diagnostic Devices                    | <input type="checkbox"/> Laboratory Equipment                |
| <input type="checkbox"/> Medical Software                               | <input type="checkbox"/> Non-active Implantable Devices      |
| <input type="checkbox"/> Ophthalmic and optical devices                 | <input type="checkbox"/> Other Categories                    |
| <input type="checkbox"/> Reusable Devices                               | <input type="checkbox"/> Single-use Devices                  |

BACK

CONTINUE

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## 6) Address and Location

Please write the  
manufacturer address.

### Address and Location

Same As Account's Address?\*

Yes

No

BACK

CONTINUE

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## 7) Communication Information

Please write the  
contact information.

### Communication Information

Same As Account's Communication Information?\*

- Yes
- No

BACK

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## 8) Technical Manager Information

Fill all the fields and attach the scientific certification and copy of documented experience certificates.

Manager Name\*

National ID Number Or Iqama\*

National ID or Iqama\*

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Issuance Date\* 

Expiry Date\* 

Scientific Certification\*

Scientific Certification\*

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Copy of Documented Experience Certificates

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

## 9) Quality Manager Information

Fill all the fields and attach the scientific certification and copy of documented experience certificates.


Manager Name\*

---

National ID Number Or Iqama\*

---

National ID or Iqama\*

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Issuance Date\*

---



Expiry Date\*


---



Scientific Certification\*


---

Scientific Certification\*

 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Copy of Documented Experience Certificates


 Attach the supporting document

Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

## 10) Attachments


Attach the requirements in  
the fields.

Copy of deed of ownership or lease contract\*




Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

Copy of industrial license\*



Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

ISO 13485 or any identical adopted standard for the same issue/version\*



Maximum file size: 25MB. Allowed file types: jpeg, jpg, pdf, png

BACK

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## 11) Payment Information

Duration and Payment  
information for the license.

License Validity (Years):	5
Expected Payment (SAR):	5000.0

BACK

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## 12) Comments & Attachments

Add your notes and attachment (optional).

Add Your Notes

---

**Add Attachment**  
Maximum total size: 50MB. Allowed file types: jpeg, jpg, pdf, png

 Attach the supporting document

+ ADD ANOTHER

**BACK** **CONTINUE** SAVE AND CONTINUE LATER CANCEL



### 13) Facility Obligations

**Agree to declaration terms and conditions.**

I have the full responsibility for all released patches and applying SFDA Quality requirements

In case of termination of my contract with the establishment/company for any reason I promise to inform SFDA within fifteen days start by last working day.

I have read the SFDA medical devices law and its interim regulation, and I promise to follow all its content and any regulations followed. Also, I promise to follow any regulation issued by SFDA in future.

This form has been filled by my knowledge with complete and correct information. Also, all attached documents are stamped by company's stamp and considered as an official copy. I take the extreme responsibility for any forgery or incorrect information on these documents.

I promise to update any changes in the current information include operating a new production line for the manufacturer.

I will not produce or market any product unless it is registered by SFDA & having a quality certificate for the manufacturer.

I agree on the declaration terms and conditions

BACK

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Request ID No.

Your request has been  
sent for review by SFDA.

Your request has been sent for review.

Request ID: 2022-

[Account Dashboard](#) | [My Requests](#)

# Thank You

