Kingdom of Saudi Arabia
Saudi Food & Drug Authority
بالأهمية نتهم
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A. Introduction

In accordance with the royal decree issued on 25/01/1428H (13 February 2007) which assigned the responsibility for regulating medical devices, *in vitro* diagnostic devices, prescription eye glasses, contact lenses and their solutions to the Saudi Food and Drug Authority (SFDA). And the council of ministers decision No. 181 on 03/06/1428H (18 June 2007) which gives the SFDA full authority to issue guidance that includes rules and procedures of registering medical devices establishments and their products.

In fulfillment of article three of the decree which appointed the SFDA to build a database for all establishments working in the field of medical devices and their products. The SFDA is pleased to launch the **Medical Devices National Registry (MDNR)** which aims at listing all Medical Devices Establishments, manufacturers, agents and suppliers dealing with medical devices, *in vitro* diagnostics, prescription eye glasses, contact lenses and their solutions and the products they deal with along with their country of origin and any premarket approval they have from other international regulatory authority.
B. What is a medical device?

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease
   - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury
   - investigation, replacement, modification, or support of the anatomy of a physiological process
   - supporting or sustaining life
   - control of conception
   - disinfection of medical devices
   - providing information for medical or diagnostic purposes by means of *in vitro*
   - examination of specimens derived from the human body
   - aids for disabled/handicapped people
   - Correction vision or protection eyes from ultra-violet rays

b) which does not achieve its primary intended action in or on the human body by pharmacologic, immunologic or metabolic means but which may be assisted in its intended function by such means.

C. Medical Devices National Registry (MDNR)

**MDNR** is a web-based enrollment scheme for medical devices establishments, manufacturers, agents and suppliers in Saudi Arabia.
All applications shall be made on-line. It consists of 2 parts. Part 1 is an account creation. Part 2 requests for information pertaining to medical devices establishments, manufacturers, agents and suppliers with respect to company profile, person responsible, medical devices particulars and pre and post-market details.

**MDNR** is not an approval system. Assignment of submission number and Registry number does not in any way constitute an admission or agreement by the **SFDA** to denote approval of an establishment and its products.

**D. Purpose of MDNR**

- To obtain a profile of the Saudi Arabia medical devices industry.
- To establish a database of all establishments, manufacturers, agents and suppliers working in the field of medical devices, in vitro diagnostics, prescription eye glasses, contact lenses and their solutions.
- To measure the readiness of medical devices establishments to comply with medical devices regulation.

**E. Who Should Enroll?**

The following parties who operate their businesses in Saudi Arabia are invited to enroll.

- Manufacturers of medical devices, *in vitro* diagnostics, prescription eye glasses, contact lenses and their solutions.
- Exporters and importers of medical devices, *in vitro* diagnostics, prescription eye glasses, contact lenses and their solutions.
- Distributors/vendors of medical devices, *in vitro* diagnostics, prescription eye glasses, contact lenses and their solutions.
F. How To Enroll?

Enrollment is online and only limited relevant information will be required. It consists of two main steps, namely:

- Step 1 : Account Creation
- Step 2 : Establishment Enrollment
  - Section A : Establishment Information
  - Section B : Authorized Person for the Establishment
  - Section C : Medical Device Information
  - Section D : Post-Market Requirements
  - Section E : Application Declaration

All applications shall be made by using the MDNR online forms and must be accompanied by relevant supporting documents as required.

The SFDA reserves the right to verify the authenticity of any submitted documents with the issuing authority or organization.

G. Security and Confidentiality of Data

All data submitted online will be protected and encrypted via the MDNR security infrastructure. All data provided will be used by SFDA.
Enrollment Scenario Guide

A. Create New Account

Through the SFDA website www.sfda.gov.sa, click on "Medical Devices". From the Medical Devices page, click on the MDNR link, or type mdnr.sfda.gov.sa in your web browser.

1. On the "MDNR" web page, click on “New Enrollment”.

2. In “New Enrollment” page fill in the fields and make sure to enter a valid e-mail address as an activation code will be sent to it.
3. Note: Password must contain at least 8 characters mixing between letters, numbers and special character to be more secure.

4. System will send an activation code to your e-mail address and display the following image.

![Activation Sent](image)

5. Note: You should complete your enrollment within one month, otherwise your account will be deleted.

6. You will receive an activation email, Click on the activation link to activate your account as shown in the following image.

![Welcome to MDNR](image)

After you click on the activation link a success message will appear, this means you can login to the system to complete your enrollment data.
B. Complete Enrollment Data.

1. Enter your username and password and then click **Login**.

2. **Section A “Establishment Information”** page will appear to complete its data. Complete the fields and make sure that you upload at least one **Document** and then Click on **Save Changes**.

3. Make Sure that all the following documents are uploaded:
   - **A. Business Registration Certificate.**
   - **B. Chamber of Commerce Certificate.**
4. After saving “Section A” successfully, you can start filling “Section B”.

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**Enroller Home**

**Section A Saved Successfully**

*Section A:*
Establishment Information

*Section B:*
Authorized Person for the Establishment

*Section C:*
Medical Device(s) Information

*Section D:*
Post-Market Requirements

*Section E:*
Application Declaration

View Application History

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5. Click on “Section B: Authorized Person for the Establishment”.
Complete the fields in this page, make sure that you upload at least One Document and then Click on “Save Changes”.
6. Make Sure that all the following documents are uploaded:
A. National Identy or Iqama.
B. Official authorization letter from the owner stamped from the company and approved from the chamber of commerce.
7. After saving “Section B” successfully go to “Section D: Post Market Requirements” to fill the requirement Data and then Click on “Save Changes”

* Note:

   **Section C** is blocked until the establishment request has been approved
POST MARKET REQUIREMENTS

Please provide a brief description and include document(s) as evidence for the following information pertaining to quality system procedure, distribution records, complaint handling, adverse incident reporting, alert and recall.

Please tick in the appropriate box / fill up the space provided

Dose your establishment has an established Quality Management System

☐ Yes  ☐ No

If your answer is 'Yes' please proceed to next question and tick against the appropriate box. If your answer is 'No' please click 'Save Changes' to proceed with the next section

Scope of Quality Management System

☐ Full quality management system covering design, production and post production processes.
☐ Partial quality management system covering design, production and production processes.

For "partial quality management system", please specify the scope

________________________________________

Please indicate your establishment quality management system by clicking the appropriate box

☑ ISO 9001:2000
☑ ISO 13485:1996
☒ ISO 13485:2003
☒ Current Good Manufacturing Practice (CGMP)
☒ Others, please specify :

Name of Certification Body

8. If your establishment has an Quality Management System you must upload the Documents.

10. After saving “Section D” successfully, you can go to “Section E” page.
11. In “Section E” you should download and print “Application Declaration Form”, fill in the form manually, sign the form and stamp it with your establishment official stamp.

**Application Declaration Form**

**Declaration by Applicant**

- **Step 1**: Please download and print the Declaration Form by clicking the link below Declaration Form (MDNR-03)
- **Step 2**: Fill in, stamp and sign form (MDNR-03)
- **Step 3**: Scan the completed Declaration Form (MDNR-03) into your computer
- **Step 4**: Upload the completed declaration form (MDNR-03) by clicking the [Upload] button

12. After filling the Declaration form manually, scan it and upload it.

13. Note the declaration Form must be Stamped and signed by authorised person and approved from Chamber of Commerce and Industry
14. Now, you’ve completed sections A, B, D, & E, your establishment request is ready to be submitted to SFDA by clicking on “Submit Application” as shown in the following figure.

15. Note: Success message will appear when establishment request is sent to SFDA.

16. After you get MDNR number for your establishment, you will be able to start filling sections (C).
17. Click on “Section C: Medical Devices Information” link, Complete the fields on this page, make sure that you upload at least one Document and then Click “Save Changes”.
18. Make sure you uploaded the product certificate “FDA, ISO, CE etc”
19. After saving “Medical Device Information” successfully, the system will show the main page of “Section C” containing a list of the current saved Device(s) with the ability to manage (add-update-delete) the list.

20. Note: You can arrange your devices the way that you like by specifying number of devices that can be showed in the table from Grouping option.

![Medical Device(s) Information](image)

21. You can add any number of medical devices and manage them from the “Section C” page. 
   For example, if we add 3 devices, it will appear on the list as in the following figure.
22. From the “Section C” page you can also search for any device name, by filling the search field with search keyword and click “Search”, and so you will get all the devices containing the entered keyword. For example, if you search about “vvv” you will get all devices that its name contains “vvv” as shown in the next figure.
C. View Application History:

1. You can view your application history by clicking on “View Application History” in the Home Page.

2. From “View Application History” page, you can check the status and History of each request as shown in the following figure.

3. You can view the history of each request by clicking on “Show” link.

4. Note: each history record contains request status, its date and if there is comments it will appear under “SFDA comments” as a link.
5. We have the following **status** for each request:

a. **Pending**: this status means that your request is still pending and waiting for SFDA action. In this status you can view and update request data.

b. **Under Study**: this status means that your request is under SFDA study and you can only view request data but can’t update it.

c. **Accepted**: this status means that your request is accepted by SFDA and you can view request data and update it (*after establishment request is accepted update in a section is considered as a separate request*).

d. **Rejected**: this status means that your request is rejected by SFDA. If request is "new enrollment" then all sections data will be in lock view and you can’t update it. Otherwise, your new request data will be deleted and return its old data.

e. **Incompleted**: this status means that your request is set as incomplete by SFDA and you should complete the missing data within a limited time and send it again to SFDA to study it.

6. **Note**: In **(Accepted – Rejected – Incompleted)** status, a notification message is going to be sent to your e-mail to notify you with **SFDA comments.**
D. Update your Account.

1. Click on "Update Account" link. On the left side.

![Update Account Image]

2. Type your **new valid** e-mail then click on "Submit" button.
3. System will show success message.

![Activation Sent Image]

4. In your mail box, you will receive an activation email to update your account.

![Activation Email Image]

5. Click on the activation link to activate your account.
6. Success message will appear to notify you that your account is activated and updated with the new e-mail address.

![Activation Page]

Your account has been activated successfully

7. Now you can login to the system using your account and you will receive all MDNR notification messages in your new e-mail address.

E. Changing Password.

1. Click on "Change Password" hyperlink. On the left side.
2. You should enter the following data:

![Change Password]

3. Note: Password must contain at least 8 characters mixing between letters, numbers and special character to be more secure.
4. After completing the fields click on "Submit" Button.
5. System will display the success message.

![Change Password]

Password updated successfully

6. Now you can login to the system using your new password.
F. Forget Password?

1. Click on Forget Password "Click Here" hyperlink. In the login area on the left side.

2. The System will display "Forget Password" page.

3. Enter your username and verification code and click on “Send Password” Button.
4. The System will send a message to your e-mail with a link to reset password.

5 Enter a new password, confirm it and then click on “Change password” button.

6. The System will display a success message and you can now login to the system using your new password.