How to apply through the MDELS

1. **MDEL Login** through the SFDA website [www.sfda.gov.sa](http://www.sfda.gov.sa), click on "Medical Devices". From the Medical Devices Page click on (MDES), then Click the (MDEL) link or type http://mdel.sfda.gov.sa in the web browser.

2. The applicant ought to use the username and password that is used in the MDNR to be able to login. The application page will appear as the following:

3. **Company Details, Authorized Contact Person and Quality Management System** will be retrieved from the MDNR system. While the **Establishment Activities** should be chosen, *Distribution or Importation or Both*. Then the Manufacturers and their Authorised Representatives must be filled as described in the following steps.
4. **Manufacturers and their Authorised Representatives Part:**

Step 1: in this section, an applicant have to click on **Add** button. Then, a new page will be opened.

Step 2: Here, you must add **ALL** your manufacturers information, while the Authorised Representatives part is not compulsory **at this stage** (add it if you are the AR).
Step 3: The added manufacturers will appear at your first page, then check the attestations boxes to be able to go to the Questionnaire.

5. **Questionnaire:** The applicant shall complete the questionnaire and upload the required documents, when there is no documents available, a brief description is must be provided.

**Notes:** please be advise that if there is a question with description field, the filed must be filled out or the submission will fail. However, the application can be saved at any time.
After the application submission, it will be processed by the SFDA and the establishment’s category will be determined based on the data provided in the application. Then, a payment request will be sent to the applicant through its email.

6. Payment:

After the payment is made, please login to the MDELS the payment details tab will be activated. The payment section shall be filled by the applicant and attach a copy of the bank transaction.

After entering the Username and Password, you would find the Payments Details tap is activated. As shown below:

Then, fill out the fields and attach a copy of your transfer.

When all these steps are completed and approved by SFDA, the license will be issued to the applicant and the application status will be changed to Licensed.