- **What are the regulatory guidelines for SFDA registrations to obtain certification?**

Kindly find the requirements to obtain Medical Device Marketing Authorization (MDMA) mentioned in (MDS-REQ1) (link)

- **Which are product codes require SFDA approval to come to Global Health Exhibition**?

Kindly find the requirements to import medical Devices for the purpose of demonstration mentioned in (MDS-REQ5) (link)

- **What is the procedure for temporary SFDA approval?**

There's no temporary approval, All Medical Devices must obtain MDMA Certificate, according to article 8 from Medical Device Law, which states "Medical devices or supplies may not be circulated unless registered and a marketing authorization is obtained."

- **Trial Import – What is the process for express license?**

Kindly find the requirements to import medical Devices for the purpose of demonstration mentioned in (MDS-REQ5) (link)

- **Are all the applications required to be in Arabic?**

All technical documents must be in English, for lay person, the information supplied by the manufacturer shall be in both the Arabic and English languages.

- **Can second-hand renew medical devices be exported to Saudi Arabia?**

Refurbished medical devices shall be treated as new medical devices and shall comply with the Medical Devices Law and the requirements of its Regulation. For more information regarding Refurbished medical devices please see Article 20 section (20.3) mentioned in (link)

- **Is it possible to obtain a special import license for a trial machine in Saudi Arabia for the Global Health Exhibition? If so, can the device be sold after the trial, or must it be returned to its country of origin?**

Kindly find the requirements to import medical Devices for the purpose of demonstration mentioned in (MDS-REQ5) (link), the demo unit must be exported after the demonstration is finished.

- **Are both US and EC standards accepted? And can a European company's product be approved if it is manufactured in China**

Kindly find the requirements to obtain Medical Device Marketing Authorization (MDMA) mentioned in (MDS-REQ1) (link), Approvals from other countries are only considered as a supporting documents.

- **Is it possible to export a device for demonstration purposes without an import license? If the hospital wants to purchase the device in KSA, what is the procedure?**

For demonstration purposes the device must obtain importation permit as mentioned in (MDS-REQ5) (link)

- **Time frame to obtain certification (min- max)?**

The evaluation time for MDMA applications is 35 working days.

- **To start a business in Saudi Arabia, is it necessary to first establish it in another prominent market and submit a commercial invoice of export together with SFDA documentation?**

Please clarify the questions and for more information regarding the Establishment licensing kindly find Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) (link)

- **Point of contact at SFDA for future enquiries and concerns?**

You can contact SFDA Medical Devices Sector on Medical Device Registration Support's email: md.rs@sfda.gov.sa