

Dears importers of medical IVDDs that have a valid Medical Devices Market authorization (MDMA)

In pursuit of the Saudi Food and Drug Authority (SFDA) in the development and delivery of all its provided services in line with the vision of the Kingdom of 2030 for a prosperous economy and an ambitious homeland. The operations sector of the SFDA has re-engineered a number of procedures to facilitate and speed up the work of investors and beneficiaries of the services provided by the SFDA to the public and private medical sector to support its participation in economic development.

Therefore, we are pleased to announce that the medical IVDD's that have a valid Medical Devices Market authorization (MDMA) from the SFDA will be cleared directly from the ports after ensuring the fulfillment of SFDA clearance conditions of SFDA are met for clearance. This does not require obtaining an import permit (MDIL) for these IVDD's, except for the following:

- MD IVDD's that have not obtained valid marketing authorization (MDMA) or even if it is under renewal or update process.
- General lab use kits that usually requested under IVDD's category in MDIL system.
- Medical IVDD's that require Ministry of Interior approval according to the Safety Data Sheet (SDS) of the products and as per the Implementing Regulations to import chemicals.

We emphasize the need to ensure that the requirements for clearance are met when the shipment arrives at the port (e.g., the presence of a heat indicator for the shipment), as well as the other requirements generally applicable in the field of importing medical laboratory reagents

If you have an inquiry, you may contact MDIL team by e-mail: md.il@sfda.gov.sa Or by Telephone 0112038222 Ext. 3906.