

- Engage with global changes in medical devices regulation during the outbreak of COVID-19, such as the regular meeting with GHWP (Global Harmonization Working Party) and IMDRF (International Medical Devices Regulators Forum) and discussing the successful stories between members in the current situation, knowledge transfers and supporting the research and development of innovative medical devices.
- Communicate with the Ministry of food and Drug Safety, addressing the following:
 1. Sharing 5 IVDDs Manufacturers developing COVID-19 tests, 3 of them already registered in SFDA database
 2. SFDA-MDS encourage local manufacturers to work closely with these Korean manufacturers in order to feed the market by COVID-19 kits
- Publish the list of EUA devices in the GHWP webpage
<http://www.ahwp.info/node/794>
- **Support countries in Medical Devices Regulation through Saudi FDA WHO Collaboration Centre for Medical Devices**

In the continuous international efforts for the SFDA WHO-Collaboration Centre of Medical Devices to help different countries in Medical Devices Regulation, Saudi FDA participated in many sessions remotely with attendance of WHO-EMERO with WHO to discuss the potential opportunities of supporting the African medical devices forum (AMDF) and provide expertise in the medical devices area during this pandemic.

The meetings are chaired by WHO secretariat in Geneva with participation from different African countries (Ghana, Tenzania, Nigeria and South Africa) in addition to experts from Saudi FDA (Dr.Razan Assaly, Dr.Mohammed Majrashi and Ms. Fajer Alkusair).

Saudi FDA participated in 4 working groups (WG1: COVID-19 IVDD tests (Mainly NAT assays), WG2 (Medical devices required during the COVID-19 outbreak including (PPE and ventilators)), WG3 (Medical devices Adverse events reports- Postmarket Surveillance) and WG4 (Guidance document in assessing MD and IVD tests donations during emergencies). Worth discussion and significant contribution was provided by Saudi FDA team including the sharing of SFDA approved IVDD tests list including EUA and MDMA as well as Safety Communication regarding the use of SFDA approved only IVDs for COVID-19 Diagnosis, published guidance for medical devices reporting and Top 10 Risky medical devices based on the risk assessment approach , Published guidance on the Requirements for Medical Masks-Recognized Standards and guidance on the requirements for Medical Devices Listing and marketing Authorization. Moreover, The SFDA will be in contact with the WGs and share any required documents or consultations through the WHO-CC.
