SFDA Regulatory Actions

- SFDA expedited the evaluation process and issuing the medical devices marketing authorization (MDMA) for the medical Personal Protective Equipment (PPE) such as medical masks, medical gloves, and single-use protective clothing to be within two working days after ensuring their safety.
- Organizing an audit visit by SFDA representative team to ensure safety and quality of raw materials and overall manufacturing processes. If the safety and quality of the manufacturing processes were accepted, a temporary permission will be provided during the urgent crisis period.
- The manufacturers shall register later with SFDA and fulfill all manufacturing requirements including ISO 13485 from accredited organizations. In addition to monitor the availability of PPE and Ventilators
- Updating Medical Devices regulation and legislations by:

1. Publish the guidance for medical masks
2. Develop an emergency guidance for using ventilators during the crisis of COVID-19
3. Coordination with the Saudi Organization for Standardization and Metrology (SASO) and the Gulf Standardization Authority to adopt the European standard for medical masks requirements (EN 14683) as a Gulf standard compatible with SFDA requirements and specifications
4. Publish a temporary guidance for Emergency Use Authorization (EUA)