Saudi FDA Regulatory requirements for Emergency Use Authorization (EUA) for IVDD and Personal Protective Equipment (PPE) during the outbreak of COVID-19

Due to the outbreak of COVID-19, The Saudi Food and Drug Authority (SFDA) has taken steps to ease importing restrictions, accelerate registration processes and provide all support for local factories and distributing companies to ensure regulations do not block the development or supply of devices that could save lives.

In order to ensure an adequate supply of medical devices and products needed are available in the kingdom, the following new regulatory interventions were applied.

1. Expedite the Approval Process for Personal Protective Equipment (PPE).

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 gowns. This step ahead the availabilities of these necessary equipments during the outbreak of COVID-19.

In addition, here are the required standards for approving the personal protective equipments (PPE):

Standards for Medical/Surgical Gloves

1. ISO 10282:2014 Single-use sterile rubber surgical gloves — Specification.
2. ISO 11193-1:2008 Single-use medical examination gloves — Part 1: Specification for gloves made from rubber latex or rubber solution

3. ISO 11193-2:2006 Single-use medical examination gloves — Part 2: Specification for gloves made from poly (vinyl chloride).

Standards for Surgical/medical and N95 respirator masks

1. EN 14683:2014 "Medical face masks. Requirements and test methods"
2. ASTM F2100 – 11(2018) "Standard specification for performance of materials used in medical face masks"
3. GSO ISO 22609:2009 "Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)"
4. ASTM F2101 – 14 "Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a biological aerosol of staphylococcus aureus"
5. ASTM F1862/F1862M – 17 "Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)"
6. SFDA.MD/ISO 10993-1:2018 "Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process"
7. SFDA.MD/ISO 10993-10:2018 "Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization"
8. ISO 11737-1:2018 "Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products"
9. EN 1041:2008+A1:2013 "Information supplied by the manufacturer of medical devices"

10. SFDA.MD/ ISO 15223-1 "Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements"

Here is the link for Guidance on Requirements for Medical Masks-recognized Standards
https://sfda.gov.sa/ar/medicaldevices/regulations/Pages/RequirementsAndConditions.aspx

2. SFDA Regulatory requirements for the approval of COVID-19 test Kits and PPE.

In the normal situation, Saudi FDA require the technical file and all supported documents in order to proceed the applications. Here are the required elements for MDMA approval:

1. Device Description and Specification, Including Variants and Accessories
    - Product and accessories identification
    - Description of the device and any accessories
    - Intended purpose of the device
    - Intended users of the device
    - Classification of the device
2. Information to be Supplied by the Manufacturer
    - Full set of labels for the device and packaging which includes the instructions for use (IFU) and any promotional material as applicable.
3. Design and Manufacturing Information
    - Full device description

- Applied parts
- Technical specifications
- Requirements documentation
- Design traceability
- Design stages
- Manufacturing processes
- Manufacturing structure

4. Essential Principles of Safety and Performance
    - Essential Principles (EPs) checklist
    - Evidence of conformance to applicable Eps
5. Benefit-risk Analysis and Risk Management
    - Benefit-risk Analysis
    - Risk Management File (RMF) in accordance to SFDA.MD/ ISO 14971
6. Product Verification and Validation
    - Test Reports
    - Biocompatibility
    - Electrical Safety & EMC
    - Evidence supporting life of product, Stability, including shelf life
    - Other Performance and Safety Reports
    - Software Verification & Validation
    - Clinical Evaluation Report / Clinical Investigation Report
7. Vigilance and Post-market Surveillance
    - Post-Market Surveillance Plan
    - Post-Market Surveillance Reports and Periodic Safety Update Report
    - Post-market Clinical Follow-up

As the current outbreak of COVID-19, Saudi FDA requires the following documents to issue EUA with the following:

1. Quality Management System (ISO 13485:2016)
2. Performance Evaluation report
3. Labeling samples
4. Testing reports
5. Attestation letter

3. List of SFDA emergency authorization (EUA) and Medical Devices Marketing Authorization (MDMA) for COVID-19.

#	Manufacturer	Kit	Approval	Type	AR
1	Roche Molecular Systems	Cobas SARS-CoV-2 test	SFDA Emergency Use Authorization (EUA) SFDA IVD (MDMA 33156) FDA EUA CE	RT-PCR	Farouk Mamoun Tamer and Co
2	Genekam	Novel Coronavirus 2020 (Wuhan Strain specific) Real time PCR	SFDA (EUA)	RT-PCR	Medical Supplies and Services Co Ltd
3	Primerdesign Ltd.	genesig Real-Time PCR COVID-19	SFDA (EUA) CE	RT-PCR	Cigalah Group Warehouse for Drug
4	BGI	Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2	SFDA (EUA) FDA EUA CE	RT-PCR	BGI HEALTH (HK) CO. LTD/ Fetal Care Medical expired AR
5	altona-diagnostic	RealStar® SARS-CoV-2 RT-PCR Kit RUO	SFDA (EUA) FDA (EUA)	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
6	Inzek International Trading BV	COVID-19 IgM/IgM Rapid Test Cassette	SFDA IVD (MDMA 26502)	Rapid	First

		(Whole Blood/Serum/Plasma)			Technology Trading Est
7	Prima Lab SA	Prima COVID-19 IgG/IgM RAPID TEST	SFDA IVD (MDMA 25555)	Rapid	Tanami Global for Business Services
8	Kogene Biotech	2019 Novel Coronavirus Real-time PCR Kit	SFDA (EUA) Korea CE	RT-PCR	High Standard Medical INC
9	TIB Molbiol Syntheselabor	Sarbecovirus E-gene	SFDA (EUA) CE	RT-PCR	Farouk Mamoun Tamer and Co
10	Becton Dickinson and Company	BD Universal Viral Transport	SFDA IVD (MDMA 23702)		Becton Dickinson BV Saudi Limited Company
11	Becton Dickinson and Company	SARS-COV-2 s Gen realtime	SFDA IVD (MDMA 33909)	RT-PCR	Becton Dickinson BV Saudi Limited Company
12	CTK Biotech Inc	On Site COVID-19 IgG/IgM Rapid Test	SFDA IVD (MDMA 31496) TGA	Rapid	WAREED ALHAYAT Est
13	Abbott Molecular Division Inc.	Abbott RealTime SARS-CoV-2 Amplification Reagent Kit Abbott RealTime SARS-CoV-2 Control Kit	SFDA IVD (MDMA 33883)	RT-PCR	Medical Supplies and Services Co Ltd
14	VIVACHEK BIOTECH (HANGZHOU) CO., LTD	VivaDiag™ COVID-19 IgM/IgG Rapid Test	SFDA IVD (MDMA 30335) TGA Singapore	Rapid	ALJEEL Medical Company
15	KogeneBiotech Co., Ltd.	PowerChek 2019-nCOV Real-time PCR Kit Real-time PCR System	SFDA IVD (MDMA 27154)	RT-PCR	High Standard Medical INC
16	1drop Inc.	1copy™ COVID-19 qPCR Kit	SFDA IVD MDMA CE	RT-PCR	Sciences and Supply limited co
17	Wuhan MGI Tech Co, Ltd	High-throughput Automated Sample Preparation System Nucleic Acid Extraction Kit Genetic Sequencer	SFDA IVD (MDMA 2020-36265)	RT-PCR	Farabi Trading Establishment

18	Lingen Precision Medical Products (Shanghai) Co., Ltd	Disposable Virus Sampling kit	SFDA IVD (MDMA 2020-37939)	Transport media	Alsana Mdeical company
19	Snibe Diagnostics	Maglumi 2019-nCoV (SARS-CoV-2) IgM/IgG kits	CE	Rapid	United Diagnostics Industry
20	QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel Single-plex real-time PCR tests for SARS-CoV-2	CE US FDA EUA	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
21	Quidel	Lyra SARS-CoV-2 Assay	SFDA EUA CE FDA EUA Health Canada	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
22	Cepheid	Xpert Xpress SARS-CoV-2 test	SFDA EUA FDA EUA	RT-PCR (Laboratory/POCT)	Abdulla Fouad for Medical Supplies and Services Company
23	Bioeksen, Buyukdere Turkey	Bio-Speedy Covid-19 QPCR detection kit / Bio-Speedy Viral Nucleic Acid Isolation kit	SFDA EUA	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
24	GUANGZHOU IMPROVE MEDICAL INSTRUMENTS CO., LTD.	Viral Preservative Medium	SFDA EUA	Transport media	Abdulla Fouad for Medical Supplies and Services Company
25	Boditech Med Inc.	AFIAS COVID-19 Ab ichroma COVID-19 Ab	SFDA MDMA (2020-39987)	Rapid	Abdulla Fouad for Medical Supplies and Services Company
26	Bioneer	AccuPower SARS-CoV-2 Real-Time RT-PCR Kit; ExiPrep 96 Viral DNA/RNA Kit; ExiPrep 96 Lite Automated NA Purification System	SFDA MDMA (2020-45979) CE	RT-PCR	High Standard Medical INC
27	CerTest	VIASURE SARS-CoV-2 Real Time PCR Detection Kit	SFDA MDMA (2020-38668) CE TGA Korea	RT-PCR	Tehama Medical Est
28	Jiangsu Rongye Technology Co., Ltd.	Viral Transport media with Swab	SFDA MDMA (2020-46115)	Transport media	Fuad Abduljalil

					alfadhli and sons Co
29	Wells Bio, Inc	careGENE™ N-CoV RT-PCR Kit; careGENE COVID-19 RT-PCR kit	SFDA MDMA (2020-36627)	RT-PCR	Dar Al Farabi Corporation for Medical DAFCO

4. Strengthening the proactive and reactive activities of Post-market surveillance

As a continuing phase after issuing EUA for COVID-19 test kits, Saudi FDA monitor the quality and performance of these devices in the market and hospitals through a wide network of connections with healthcare providers and regulatory affairs officers in Saudi. Moreover, SFDA increases the communication channels with healthcare professionals and feeding them by up to date recommendations and Safety Communications such as:

- Best practices when using masks and gowns during the COVID-19 outbreak
- Teleworking in health sector during COVID-19 emergency regarding to health care services and medical applications provided via teleworking strategy, include exchange and transfer health data, which may increase during a wide-scale public emergency such as that caused by the (COVID-19) virus and through exchange information between SFDA & international health organizations in the field of medical device safety.
- Ventilator Supply Mitigation Strategies during the outbreak of COVID-19
- Issues to be Encountered through reusable and single use medical devices
- Recommendations of Non-contact Infrared Thermometers during (COVID-19)
- Warning of IVDs Unauthorized Test Kits for Diagnose (COVID-19)

- (COVID-19) Requests for Information Regarding the Off-label use of GE Healthcare Anesthesia Devices for ICU ventilation
- Usage of Draeger Anesthesia Devices for Long-term Ventilation
- Ventilating ICU Patients Using Flow-i, Flow-c and Flow-e Anesthesia Machines: