

## **Saudi FDA effective communications efforts and Regulatory requirements for Emergency Use Authorization (EUA) for IVDD and Personal Protective Equipment (PPE) during the Pandemic 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.

### **SFDA International Efforts**

- 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

- **SFDA International Efforts to 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.

### **SFDA Regulatory efforts**

## **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

In addition, here is the link for published SFDA Guidance on General Requirements for Medical Devices Manufacturing (

<https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/GeneralRequirementsM D-Manufacturing-e.pdf>) and Guidance Requirements for Ventilators, Ventilator Tubing

Connectors and ventilator Accessories –Recognized Standards

(<https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MDS%E2%80%93G47 e.pdf>)

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

#### SFDA Approval

#### International Approvals

#	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) Realtime 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 Company
6	Inzek International Trading BV	COVID-19 IgM/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	SFDA IVD (MDMA 26502)	Rapid	First 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)	Transport media	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	OnSite 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 FDA EUA	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	SFDA MDMA (2020-28765) CE	Immunoassay	United Diagnostics Industry
20	QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel Single-plex real-time PCR tests for SARS-CoV-2	SFDA MDMA (2020-39975) CE US FDA EUA	RT-PCR	Abdulla Fouad Company
21	Quidel	Lyra SARS-CoV-2 Assay	SFDA MDMA (2020-47739) 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	Bioeksan, 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)	Immunoassay	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 ABDUL JALIL AL FADHLI AND SONS TRADING 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
30	SD Biosensor, Inc.	STANDARD M nCoV Real-Time Detection Kit	SFDA MDMA (2020-32762) FDA EUA	RT-PCR	AlKamal Import Office
31	Abbott Ireland Diagnostics Division	-SARS-CoV-2 IgG Reagent Kit -SARS-CoV-2 IgG Calibrator Kit -SARS-CoV-2 IgG Control Kit	SFDA MDMA (2020-46442)	Rapid	Medical Supplies and Services Co Ltd
32	King Faisal Specialist Hospital & Research Centre	SARS-CoV-2 SYBER® Green rtPCR SARS-CoV-2 Nested PCR	SFDA EUA	RT-PCR	King Faisal Specialist Hospital & Research Centre
33	Roche Diagnostics	Elecsys Anti-SARS-CoV-2	SFDA MDMA (2020-48744) FDA EUA	Immunoassay	Roche Diagnostics Saudi Arabia Limited
34	BIOMERIEUX S.A.	ARGENE® SARS-COV-2 R-GENE®	SFDA MDMA (2020-37990)	RT-PCR	ALJEEL MEDICAL COMPANY
35	Shenzhen Lifotronic Technology Co., Ltd.	SARS-CoV-2 IgM (Electrochemiluminescence Immunoassay)	SFDA MDMA (2020-43328)	ECLIA	Yood Company

		SARS-CoV-2 IgG (Electrochemiluminescence Immunoassay)			
36	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd.	SARS-CoV-2 IgG (CLIA) SARS-CoV-2 IgM (CLIA)	SFDA MDMA (2020-47379)	CLIA	Abdulla Fouad For Medical Supplies and Services Company
37	Becton Dickinson and Company	BD SARS-CoV-2 Reagents for BD MAX System	SFDA MDMA (2020-40517)  CE  FDA EUA	RT-PCR	Becton Dickinson B.V Saudi Limited Company
38	VIRCELL, S.L	-COVID-19 ELISA IgG -COVID-19 ELISA IgM+IgA -COVID-19 VIRCLIA IgG MONOTEST -COVID-19 VIRCLIA IgM+IgA MONOTEST	SFDA MDMA (2020-45823)	ELISA	Abdulla Fouad For Medical Supplies and Services Company
39	Ortho Clinical Diagnostics, Inc.	- VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 total reagent pack - VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 total Calibrator - VITROS® Immunodiagnostic Products Anti-SARS-CoV- 2 Total Controls	SFDA MDMA (2020-44842)  FDA EUA	ELISA	Samir Trading and Marketing CJSC
40	Guangzhou Deaou Bio-technology co.,Ltd	Virus Sampling Tube	SFDA MDMA (2020-38297)	Transport medium	ALOSOOL MEDICAL TRADING COMPANY
41	Bosch Healthcare Solutions GmbH	Vivalytic one	SFDA MDMA (2020-41155)	Nucleic Acid extraction	Binary System Medical Co
42	Lana Al Khaleej Al Awal for medical supplies	NATEJAH New Coronavirus (COVID-19) IgG/IgM Rapid Test	SFDA MDMA (2020-32275)	Rapid	Lana Al Khaleej Al Awal for medical supplies

43	King Abdulaziz Medical City (NGHA)	SARS-CoV-2 Multiplex One Step RT-PCR	SFDA EUA	RT-PCR	King Abdulaziz Medical City (NGHA)
44	Life Technologies Corporation	- TaqPath COVID-19 Control Dilution Buffer - TaqPath COVID-19 RT-PCR Kit - TaqPath COVID-19 Control - TaqPath 1-Step Multiplex Master Mix	SFDA MDMA (2020-46522)	RT-PCR	Intgerated Gulfbiosystems
45	OSANG Healthcare	GeneFinder™ COVID-19 Plus RealAmp Kit	FDA EUA CE	RT-PCR	ELITECHGROUP B.V. Netherlands / AIKamal Import Office ELITechGroup Inc. USA / Bio Standards ELITechGroup S.p.A Italy / Bayouni Trading Co. Ltd. (expired)
46	Veredus Laboratories	VereCoV Detection Kit	Singapore	RT-PCR	N/A
47	Co-Diagnostics	Logix Smart COVID-19 Test	CE US FDA EUA	RT-PCR	N/A
48	BGI	Real-Time Fluorescent RT-PCR kit for detecting SARS-CoV-2	CE FDA EUA	RT-PCR	BGI HEALTH (HK) CO. LTD/ Fetal Care Medical expired AR
49	Avellino	Avellino SARS-CoV-2/COVID-19 Test (AvellinoCoV2 for short)	FDA EUA	RT-PCR	N/A
50	IDbyDNA Inc.	Explify Respiratory test		RT-PCR	N/A

51	Surgisphere Corporation	COVID-19 Diagnosis Decision Support Tool		Rapid	N/A
52	Sentinel Diagnostics	STAT-NAT COVID-19 assay		RT-PCR	Farouk Mamoun Tamer and Co Medical Supplies and Services Co Ltd Arabian Medical and Pharmaceutical Co Beckman Coulter Saudi Arabia Co Ltd
53	NeuMoDx Molecular	NeuMoDx SARS-CoV-2 Assay	FDA EUA	RT-PCR	Abdulla Fouad For Medical Supplies and Services Company
54	ARUP Laboratories	COVID-19	USA (Lab test; EUA planned)	RT-PCR	N/A
55	A*STAR, Tan Tock Seng Hospital of Singapore	A*STAR Fortitude 2.0	Singapore	RT-PCR	N/A
56	BioReference Laboratories	Novel Coronavirus COVID-19	USA (Lab test; EUA planned)	RT-PCR	N/A
57	Centers for Disease Control and Prevention (performed at qualified high-complexity CLIA laboratories designated by CDC)	CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC)	FDA EUA	RT-PCR	N/A
58	Genomica/PharmMar Group	2 kits: qCOVID-19, CLART COVID-19	CE	RT-PCR	N/A

59	Hackensack Meridian Health CDI	SARS-COV-2 test	USA (Lab test; preliminary EUA, New Jersey DOH approval)	Rapid	N/A
60	Integrated DNA Technologies/Danaher	IDT 2019-novel coronavirus kit	USA (test kit; Under CDC FDA EUA)	RT-PCR	N/A
61	Laboratory Corporation of America (LabCorp)	COVID-19 RT-PCR test	FDA EUA	RT-PCR	N/A
62	NorthShore University HealthSystem	Novel Coronavirus test	USA (Lab test; EUA planned)	-	N/A
63	Northwell Health	2019 Novel Coronavirus PCR	USA (Lab test; EUA planned)	RT-PCR	N/A
64	Novacyt/Primerdesign	COVID-19 coronavirus test	CE FDA EUA	RT-PCR	Arabian Medical Hospital Supply Co Ltd
65	NY State Department of Health (performed at Wadsworth Center and New York City Department of Health and Mental Hygiene, Public Health Laboratories)	New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel	FDA EUA	RT-PCR	N/A
66	Quest Diagnostics	Coronavirus Disease 2019 (COVID-19) Test	FDA EUA	RT-PCR	N/A
67	Seegene	Allplex 2019-nCoV Assay	FDA EUA	RT-PCR	Bayouni Trading Company

			CE TGA Korea		
68	Stanford Clinical Virology Laboratory	SARS-CoV-2 RT-PCR test	USA (Lab test; EUA planned)	RT-PCR	N/A
69	University of Washington Medicine Clinical Virology Lab	SARS-CoV-2 PCR test	USA (Lab test; EUA planned)	RT-PCR	N/A
70	Viracor Eurofins	Coronavirus SARS-CoV-2 RT-PCR assay	USA (Lab test; EUA planned)	RT-PCR	N/A
71	Zhejiang Orient Gene Biotech	COVID-19 IgG/IgM Rapid Test	CE notified US FDA	Rapid	Golden Care Medical Establishment (Expired)
72	Diagnostic Solutions Laboratory	COVID-19 Assay	US FDA EUA submitted	Rapid	N/A
73	Hologic	Panther Fusion SARS-CoV-2 assay	FDA EUA TGA	RT-PCR	ALJEEL MEDICAL COMPANY
74	3D Medicines	two kits, 2019-nCoV RT-qPCR	CE	RT-PCR	N/A
75	Anatolia Genetworks	Bosphore Novel Coronavirus (2019-nCoV) Detection Kit	CE	RT-PCR	N/A
76	Diatherix Eurofins	COVID-19 Panel		RT-PCR	N/A
77	Fulgent Genetics/MedScan Laboratory	COVID-19	USA (Lab test; EUA planned)	RT-PCR (Laboratory/POCT)	N/A
78	Systaaq Diagnostic Products	2019-Novel Coronavirus (COVID-19) Real Time PCR Kit	CE	RT-PCR	N/A

79	UPMC	COVID-19 test		RT-PCR	N/A
80	Abbott	ID Now COVID-19	FDA EUA	isothermal amplification	Medical Supplies and Services Co Ltd
81	Abbott	Abbott RealTime SARS-CoV-2 EUA test	FDA EUA	RT-PCR	Medical Supplies and Services Co Ltd
82	Luminex Molecular Diagnostics, Inc.	NxTAG CoV Extended Panel Assay	FDA EUA	RT-PCR	Hatem I Alshedwy Commercial Est
83	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit	FDA EUA CE	RT-PCR	N/A
84	Mesa Biotech Inc.	Accula SARS-Cov-2 Test	FDA EUA	RT-PCR	N/A
85	BioFire Defense, LLC / BioMérieux	BioFire COVID-19 Test	FDA EUA	RT-PCR	ALJEEL MEDICAL COMPANY
86	GenMark Diagnostics, Inc.	ePlex SARS-CoV-2 Test	FDA EUA	RT-PCR	N/A
87	DiaSorin Molecular LLC	Simplexa COVID-19 Direct assay	FDA EUA	RT-PCR	Abdulla Fouad for Medical Supplies and Services Company
88	Assure Tech	COVID-19 IgG/IgM Rapid Test Device	notified US FDA CE	Rapid	Farabi Trading Establishment
89	AusDiagnostics	AusDiagnostics SARS-CoV-2, influenza, RSV panel	TGA Korea	RT-PCR	N/A
90	Autobio Diagnostics	Anti-SARS-CoV-2 Rapid Test	US FDA EUA	Rapid	N/A
91	BioMedomics	COVID-19 IgM-IgG Rapid Test	notified US FDA	Rapid	N/A
92	BTNX	Rapid Response COVID-19 IgG/IgM Test Cassette	notified US FDA	Rapid	Target2 Trading Establishment
93	Core Technology	CoreTest COVID-19 IgM/IgG Ab Test	notified US FDA	Rapid	WAREED ALHAYAT Est



94	Credo Diagnostics Biomedical	VitaPCR SARS-CoV2 Assay	CE	RT-PCR	N/A
95	DiaCarta	QuantiVirus SARS-CoV-2 test	CE US FDA EUA	RT-PCR	N/A
96	Diazyme Laboratories	Diazyme DZ-LITE SARS-CoV-2 IgG, IgM CLIA Kits	notified US FDA	Rapid	Taaml Trading Company
97	Euroimmun/PerkinElmer	Anti-SARS-CoV-2 ELISAs (IgA and IgG)	FDA EUA CE	Rapid	Medical Regulations Gate
98	Guangzhou Wondfo Biotech	SARS-CoV-2 Antibody Test	TGA notified US FDA	Rapid	Regulatory Standards Est
99	Hackensack Meridian Health CDI	SARS-COV-2 test	USA (Lab test; EUA planned)	RT-PCR	N/A
100	Hangzhou Biotest Biotech	COVID-19 IgG/IgM Rapid Test Cassette	TGA notified US FDA	Rapid	Arab Circle Healthcare
101	Hangzhou Clongene Biotech	Clungene COVID-19 IgM/IgG Rapid Test Cassette	TGA notified US FDA	Rapid	N/A
102	Hangzhou Testsealabs Biotechnology	One Step SARS-CoV2 (COVID-19) IgG/IgM Test	notified US FDA	Rapid	N/A
103	Healgen Scientific	COVID-19 IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	notified US FDA	Rapid	N/A
104	Innovita (Tangshan) Biological Technology	2019-nCoV Ab Test (Colloidal Gold)	notified US FDA	Rapid	Medical Centers Company Ltd
105	Jiangsu Macro & Micro-Test Med-Tech	SARS-CoV-2 IgM/IgG Rapid Assay Kit (Colloidal Gold)	notified US FDA	Rapid	N/A
106	JN Medsys	ProTect Covid-19 kit	Singapore	RT-PCR	N/A
107	LGC, Biosearch Technologies	2019-nCoV CDC-qualified Probe and Primer Kits for SARS-CoV-2		RT-PCR	N/A
108	Medical Systems Biotechnology	Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit	notified US FDA	Rapid	N/A

109	Nirmidas Biotech	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	notified US FDA	Rapid	N/A
110	Phamatech	COVID19 IgG/IgM Rapid Test	notified US FDA	Rapid	N/A
111	Promedical	COVID-19 Rapid Test, Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	notified US FDA	Rapid	N/A
112	SD Biosensor	Standard Q COVID-19 IgM/IgG Duo	notified US FDA	Rapid	AlKamal Import Office
113	Shanghai Fosun Long March Medical Science/Shanghai Fosun Pharmaceutical	novel coronavirus nucleic acid detection kit	CE	RT-PCR	N/A
114	SolGent	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection kit	CE Korea		N/A
115	Suzhou Kangheshun Medical Technology	SARS-CoV-2 IgG/IgM Rapid Test Cassette	notified US FDA	Rapid	N/A
116	Telepoint Medical Services	SARS-CoV-2 IgG/IgM Rapid Qualitative Test	notified US FDA	Rapid	N/A
117	United Biomedical	UBI SARS-CoV-2 ELISA	notified US FDA	Rapid	N/A
118	Vision Medicals	SARS-CoV-2 Clinical Sequencing assay	CE		N/A
119	Zhengzhou Fortune Bioscience	IgG/IgM Antibody Rapid Test Kits (Colloidal Gold Immunochromatography method)	notified US FDA	Rapid	N/A
120	Zhuhai Encode Medical Engineering	Novel Coronavirus (COVID-19) IgG/IgM Rapid Test Device	notified US FDA	Rapid	N/A
121	Zhuhai Livzon Diagnostics	Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-CoV-2) (Colloidal Gold)	notified US FDA	Rapid	N/A
122	Shanghai ZJ Bio-Tech Co Ltd	Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 genes)	TGA	RT-PCR	N/A
123	Beijing Wantai Biologicalpharmacy Enterprise Co Ltd	Wantai SARS-CoV-2 Ab Rapid Test kit	TGA	Rapid	Rose Aljazera Company
124	AITbiotech Pte Ltd	abTESTM COVID-19 qPCR I Kit	Singapore	RT-PCR	N/A

125	DSO National Laboratories	Real-Time PCR Assay for the Detection of SARS-CoV-2 Virus	Singapore	RT-PCR	N/A
126	Biolidics Limited	Nanjing Vazyme 2019-nCoV IgG/IgM Detection Kit	Singapore	Rapid	N/A
127	Biowalker Pte Ltd	Kit for Novel- Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)	Singapore	RT-PCR	N/A
128	3B BlackBio Biotech India Ltd	TRUPCR® SARS-CoV-2 RT qPCR Kit	research use only (RUO)	RT-PCR	N/A
129	AB ANALITICA	REALQUALITY RQ-2019-nCoV	CE	RT-PCR	N/A
130	Acumen Research Laboratories Pte. Ltd	Acu-Corona 2.0	Singapore	RT-PCR	N/A
131	ADT Biotech	LyteStar 2019-nCoV RT-PCR Kit 1.0	research use only (RUO)	RT-PCR	N/A
132	Ampligene India Biotech	AmpEZ Rapid and Sensitive Realtime Covid-19 Test	research use only (RUO)	RT-PCR	N/A
134	Atila BioSystems, Inc.	iAMP COVID-19 Detection Kit	FDA EUA	RT-PCR	N/A
135	Sansure Biotech, Inc.	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit	FDA EUA CE China FDA-EUA	RT-PCR	N/A
136	Shanghai GeneDx Biotechnology Co., Ltd	Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit	China FDA-EUA	RT-PCR	N/A
137	Shanghai ZJ Bio-Tech Co., Ltd/Liferiver	Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCRT kit	CE China FDA-EUA	RT-PCR	N/A
138	Wuhan Easydiagnosis Biomedicine Co., Ltd	SARS-CoV-2 nucleic acid test kit	CE China FDA-EUA	RT-PCR	N/A
139	Cellex Inc.	qSARS-CoV-2 IgG/IgM Rapid Test	FDA EUA	Rapid	N/A
140	Ipsium Diagnostics, LLC	COV-19 IDx assay	FDA EUA	RT-PCR	N/A
141	Luminex Corporation	ARIES SARS-CoV-2 Assay	FDA EUA	RT-PCR	Hatem I Alshedwy Commercial Est

142	ScienCell Research Laboratories	ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit	FDA EUA	RT-PCR	N/A
143	Gnomegen LLC	Gnomegen COVID-19 RT-Digital PCR Detection Kit	FDA EUA	RT-PCR	N/A
144	InBios International, Inc	Smart Detect SARS-CoV-2 rRT-PCR Kit	FDA EUA	RT-PCR	N/A
145	Chembio Diagnostic System, Inc	DPP COVID-19 IgM/IgG System	FDA EUA	Rapid	N/A
146	Mount Sinai Laboratory	COVID-19 ELISA IgG Antibody Test	FDA EUA	Rapid	N/A
147	Maccura Biotechnology (USA) LLC	SARS-CoV-2 Fluorescent PCR Kit	FDA EUA	RT-PCR	N/A
148	GenoSensor, LLC	GS™ COVID-19 RT-PCR KIT	FDA EUA	RT-PCR	N/A
149	KorvaLabs Inc.	Curative-Korva SARS-Cov-2 Assay	FDA EUA	RT-PCR	N/A
150	Fosun Pharma USA Inc.	Fosun COVID-19 RT-PCR Detection Kit	FDA EUA	RT-PCR	N/A
151	Trax Management Services Inc.	PhoenixDx 2019-CoV	FDA EUA	RT-PCR	N/A
152	DiaSorin Inc.	LIAISON SARS-CoV-2 S1/S2 IgG	FDA EUA	Rapid	Abdulla Fouad for Medical Supplies and Services Company
153	SEASUN BIOMATERIALS	U-TOP COVID-19 Detection Kit	FDA EUA	RT-PCR	N/A
154	Bio-Rad Laboratories	Platelia SARS-CoV-2 Total Ab assay	FDA EUA	Rapid	Abdulrehman Algozaibi GTC
155	Rheonix, Inc.	Rheonix COVID-19 MDx Assay	FDA EUA	RT-PCR	N/A
156	LabGenomics Co., Ltd.	LabGun COVID-19 RT-PCR Kit	FDA EUA	RT-PCR	N/A
157	Wadsworth Center, New York State Department of Health	New York SARS-CoV Microsphere Immunoassay for Antibody Detection	FDA EUA	Rapid	N/A
158	BioFire Diagnostics, LLC	BioFire Respiratory Panel 2.1 (RP2.1)	FDA EUA	RT-PCR	ALJEEL MEDICAL COMPANY
159	Bio-Rad Laboratories, Inc.	Bio-Rad SARS-CoV-2 ddPCR Test	FDA EUA	RT-PCR	Abdulrehman Algozaibi GTC
160	Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company)	FTD SARS-CoV-2	FDA EUA	RT-PCR	Intgerated Gulfbiosystems

161	BioMérieux SA	SARS-COV-2 R-GENE	FDA EUA	RT-PCR	ALJEEL MEDICAL COMPANY
162	Sherlock BioSciences, Inc.	Sherlock CRISPR SARS-CoV-2 Kit	FDA EUA	RT-PCR	N/A
163	OPTI Medical Systems, Inc.	OPTI SARS-CoV-2 RT PCR Test	FDA EUA	RT-PCR	N/A
164	Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay	FDA EUA	RT-PCR	N/A
165	Zymo Research Corporation	Quick SARS-CoV-2rRT-PCR Kit	FDA EUA	RT-PCR	N/A
166	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit	FDA EUA	RT-PCR	N/A
167	Quidel Corporation	Sofia 2 SARS Antigen FIA	FDA EUA	Antigen	Abdulla Fouad for Medical Supplies and Services Company

#### 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.
- Monitor the effectiveness of Rapid IVD tests for COVID-19 in Saudi Market
- Recommendations to Safe use of Aerosol intubation box.

In addition to the effective communications with healthcare providers, another channels were created to enhance the responses with manufacturers, Authorized representatives and Public:

### **Effective Communications with Manufacturers and Authorized Representatives**

- Answering all received inquiries from local / international manufacturers and authorized representatives relating to surgical masks, ventilators, Infrared thermometers and IVDD kits for COVID-19
- Communicate with Ventilators' manufacturers and their authorized representatives to ensure safety, efficacy, and performance of the devices, perform maintenance if needed.



### **Effective Activities with Media and Public**

- Conduct online webinar addressing the SFDA-MDS efforts to manage the outbreak of COVID-19
- Publish awareness material about the Infrared thermography imaging systems.
- Remotely Electronic webinar ( Safe use of ventilators)
- Remotely Electronic webinar ( SFDA requirements for safe use of medical devices at Radiology, nuclear Medicine , radiation therapy departments and cosmetics clinics)
- Remotely Electronic webinar (Recommendation to avoid the transmission of COVID-19 through reusable devices and SUDs )
- Remotely Electronic webinar ( Infrared thermometers)
- Remotely Electronic webinar ( Safe use of medical devices at healthcare facilities)
- Publish article about Medical Devices' effective communications efforts in SPSC newsletter
- Publish a scientific statement about sterilization tunnels by using disinfectant and UV