

List of Emergency Use Approved medical devices

License number	Date of issuance	Device name	Device Model	Risk Classification	Physical Manufacturer	Legal Manufacturer	Authorized Representative
EUA-2021-0002	02-Jun-21	SARS-CoV-2 Rapid Antigen Test	9901-NCOV-01G	Other IVD	SD Biosensor, Inc. 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA	SD Biosensor, Inc. C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA	General Medical W.L.L.
EUA-2021-0003	03-Oct-21	Celltrion DiaTrust COVID-19 Ag Rapid Test	CT-P60 D-2 02		Humasis Co, Ltd. Rm. 114,502,504,604,604-1,803-2, 88, Jeonpa-ro, Dongangu, Anyang- si, Gyeonggi-do, 14042, Republic of Korea	Humasis Co, Ltd. Rm. 114,502,504,604,604-1,803-2, 88, Jeonpa-ro, Dongangu, Anyang- si, Gyeonggi-do, 14042, Republic of Korea	Nasser Pharmacy WLL
EUA-2022-0001	29-Nov-22	Panbio™ COVID-19/Flu A&B Rapid Panel (Nasopharyngeal)	62FK10	Other IVD	Abbott Diagnostics Korea Inc., 65, Borahagal-ro, Gilheung-gu, Yongin-si, Gyeonggi-do, 17099, Republic of Korea	Abbott Rapid Diagnostics Jena GmbH Orlaweg 1, D-07743 Jena, Germany	GULF PHARMACIES W.L.L