



## CLASSIFICATION LETTER

### DRUG DEPARTMENT

Application No: DRCLAS-2022-000359

Issue Date: 20/01/2022

Expiry Date: 19/01/2025

M/S.:

Dear Sirs,

This is to inform you that the Classification Committee M. No.: 01/2022 Dated 20/01/2022 has classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
SGTi-flex Covid 19 Ag, Rapid Test Kit	Sugentech Inc. Chungcheongbuk-do, Korea (South)	CLEARANCE FROM UAE MINISTRY OF HEALTH & PREVENTION AS OVER THE COUNTER MEDICAL DEVICE.  IMPORT/EXPORT ONLY BY MOHAP LICENSED MEDICAL STORE.  READ THE BELOW INSTRUCTIONS

- This letter is used only to classify a Product in order to guide the applicant to which regulatory path to follow in the UAE, this is not a marketing authorization certificate.
- This test cannot be depended on solely to confirm a positive or negative result for Covid 19 testing.
- Patients tested as Covid-19 positive by the Rapid Test Kit must be referred for a confirmatory RT-PCR Test in a certified laboratory.
- For importation the applicant has to approach the Importation section/ Drug Department at the UAE MOHAP (Online) for clearance as per applicable procedures after submitting a copy of this letter with copies of quality related documents e.g.: ISO, CE etc.
- Such products will only be cleared for Medical Stores licensed by the UAE MOHAP.
- The product is allowed to be placed in pharmacies for OTC sale for personal use.
- In case of any malfunction of the cleared Medical Devices then the Agent/Applicant is responsible to notify MOHAP immediately, failing to do so will hold the Agent/Applicant liable.
- For Medical Devices containing Software that processes patient data, it is mandatory to be in compliance with all applicable legislations.
- MOHAP did not analyze the product and doesn't guarantee the quality, efficacy & safety of the product.
- This letter was given for the purpose of preliminary classification based on data submitted by the applicant, the applicant alone bears the responsibility of the truth of submitted data, MOHAP doesn't bear any responsibility.

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