



Plant: 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, Korea  
HQ: 107, Ihyeon-ro 30beon-gil, Giheung-gu Yongin-si, Gyeonggi-do, Korea

TEL. +82 - 43 - 879 - 2949  
FAX. +82 - 43 - 879 - 2991

## Letter of confirmation

21 Oct. 2021

To Whom it may concern at ONAC,

We, Green Cross Medical Science Corporation (GCMS), with business registration number 135-81-67475, are certified by the Ministry of Health and Drug Safety in Korea as the legal manufacturer of the GENEDIA W COVID-19 Ag rapid test kit.

We hereby confirm:

1. Changes in the product specification and the management of the risk concerning production and distribution of the product is in our responsibility is respect to product safety and conformity in accordance with IVD Directive 98/79/EC.
2. The claimed period of shelf-life an on-going effort to extend from 6 months up to 24 months by submitting the prolonged real-time stability test data. The latest report. MB-01-0643-07-08 was created on 2021-07-22.
3. The production from the first Lot 643G2001 to the Lot 643G2048 (Numbers are referred sequentially) with one (1)-year expiration date claims shall be regarded as same as production lots after 643G2049 with two (2)-year expiration date, especially with regards to its performance statements such as sensitivity and specificity. That statement has been notified by manufacture' letter on 2021-10-08.
4. As the repacking process by the local distributor in Romania was covering only the activities of adding Romanian IFU inside the packing box and bringing Romanian sticker outside of the packing box, we confirm that the packing process will not have any negative affect on the performance of the test.
5. The shelf-life extension has been claimed for 24 months from 12 months and the requested shelf-life guarantee for 12 months from the date of the delivery through the distributor is within the extended shelf-life, the 12 months of shelf-life can be guaranteed by GCMS
6. The responsibility of manufacturer to notify and to share all the essential information with our European Authorization Representative has been fulfilled and recorded accordingly.

Thank you for your cooperation.

Sincerely yours,

A handwritten signature in blue ink that reads "Jongkwan Ko".

**Jong-Kwan, Ko**

Registered Quality Manager, Quality Assurance  
Authorized representative of manufacturer