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Ihr Zeichen, Ihre Nachricht vom	Unser Zeichen, unsere Nachricht vom	Name	Datum
		[CMO]	2021-10-21

GENEDIA W COVID-19 Ag / Stability test report & Extension of shelf-life

Dear ladies and gentlemen
To whom it may concern

In the capacity of European Authorized Representative under IVD Directive 98/79/EC of the manufacturer Green Cross Medical Science Corporation (Korea), we hereby confirm that we have received from the manufacturer

1. Report 'Stability Studies GENEDIA W COVID-19 Ag',
   dated 2021-07-22 and
2. Letter of statement' concerning extension of shelf-life from 12 months to 24 months,
   dated 2021-10-08

As an European Authorized Representative, it is not our responsibility to review the report for correctness and conformity.
Changes in the product specification shall be evaluated and validated by the manufacturer with respect to product safety and conformity in accordance with IVD Directive 98/79/EC.
The responsibility for product safety and compliance lies solely with the manufacturer. The technical documentation must be updated accordingly.

The contents or results of the report have no effect on the registration status with the competent authority in Germany.

The above documents are uploaded by the manufacturer to our document server system as part of the technical documentation and can be provided to a competent authority in the EEA on request.

Best regards,

Clemens Mohr |
Director European Regulatory Affairs |
Diplom Engineer (FH) Biomedical Engineering |
MT Promedt Consulting GmbH |