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Ihr Zeichen, Ihre Nachricht vom

Unser Zeichen, unsere Nachricht vom

Name
[CMO]

Datum
2021-10-14

GENEDIA W COVID-19 Ag / Stability test report

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 the report "Stability Studies GENEDIA W COVID-19 Ag " (document number MB-01-0643-07-08) dated 2021-07-22.

As an European Authorized Representative, it is not our responsibility to review this 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.

In accordance with the current requirements of the Directive and national legislation, the Technical Documentation is sent to the competent authorities only upon request.

Best regards,

MT Promedt Consulting GmbH

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

geschäftsführer |

christoph leder
dr. michael rinck
gerichtsstand | legal venue: saarbrücken | germany

handelsregister |

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bankverbindung |

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