



# Certificate of EU product notification

Herewith we confirm that

**MT Promedt Consulting GmbH**  
**Altenhofstraße 80**  
**66386 St. Ingbert**  
**Germany**

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

**Green Cross Medical Science Corp.,**  
**26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun,**  
**Chungcheongbuk-do, 27632**  
**Republic of Korea**

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).

The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

4 September 2020

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Dr. Michael Rinck  
- Managing Director -

**Enclosure**  
Annex I



**Green Cross Medical Science Corp.,**

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

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<b>Internal Reference Number</b>	<b>Product Name (Model name)</b>	<b>Registration Number (at the German CA/DIMDI) DE/CA70/40838/</b>	<b>Product Category (EDMS)</b>	<b>EDMS Code Description</b>	<b>Classification Annex</b>
GCM-07	GENEDIA W COVID-19 IgM/IgG	157873	15 04 80 90 00	Other Viral Antigen/Antibody Detection	III
GCM-07-01	GENEDIA W ONE COVID-19 IgM/IgG	157873	15 04 80 90 00	Other Viral Antigen/Antibody Detection	III
GCM-07-02	GENEDIA W COVID-19 Ag	157873	15 04 80 90 00	Other Viral Antigen/Antibody Detection	III
GCM-08	GENEDIA W COVID-19 Real-Time RT-PCR Kit	156264	16 90 90 01 90	Other Other Genetic Tests	III
GCM-13	GENEDIA W COVID-19 Colorimetric LAMP premix Kit	157096	15 04 40 90 00	Other Virology - NA Reagents	III

4 September 2020

Dr. Michael Rinck  
- Managing Director -