



# 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

**RapiGen Inc.**  
**3-4F, 16, LS-ro 91beon-gil, Dongan-gu,**  
**Anyang-si, Gyeonggi-do 14119**  
**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



## RapiGen Inc.

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

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Internal Reference Number	Product Name (Model name)	Registration Number (at the German CA/DIMDI) DE/CA70/40838/	Product Category (EDMS)	EDMS Code Description	Classification Annex
RAP-01-10	BIOCREDIT COVID-19 Ag	157030	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD/ Annex III
RAP-01-11	BIOCREDIT COVID-19 IgG+IgM Duo	157030	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD/ Annex III
RAP-01-12	BIOCREDIT COVID-19 IgG+IgM Combo	157030	15 70 90 90 00	Other Other Virology Rapid Tests	Other IVD/ Annex III

4 September 2020

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Dr. Michael Rinck  
- Managing Director -