



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

PRIME4DIA Co., Ltd.
#930, 415 Heungan-daero,
Dongan-gu, Anyang-si,
Gyeonggi-do, 14059
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.

29 May 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I



PRIME4DIA Co., Ltd.

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
PRD-01	P4DETECT COVID-19 IgM/IgG	156047	15 04 80 90 00	Other Viral Antigen / Antibody Detection	Other IVD / Annex III

29 May 2020

Dr. Michael Rinck
- Managing Director -