



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

Asan Pharmaceutical Co., Ltd. 122-26 Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do 17551 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.

3 December 2020

Dr. Michael Rinck - Managing Director -

Enclosure Annex I





Asan Pharmaceutical Co., Ltd.

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

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Internal Number	Registration Number (at the German CA/ DIMDI)	Product Category (EDMS)	EDMS Code Description	Classification Annex
ASA-01	DE/CA70/40838-159662	15 70 90 90 00	Other Other Virology Rapid Test	Other IVD / Annex III
ASA-02	DE/CA70/40838-157494	15 04 80 04 00	Influenza & Para Influenza	Other IVD / Annex III
ASA-03	DE/CA70/40838-157496	14 01 02 20 00	Transport Media (Tubes)	Other IVD / Annex III
ASA-04	DE/CA70/40838-158473	16 90 90 01 90	Other Other Genetic Tests	Other IVD / Annex III

3 December 2020

Dr. Michael Rinck (

- Managing Director -