



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.

5 October 2020

Dr. Michael Rinck
- Managing Director -

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Enclosure
Annex I



Asan Pharmaceutical Co., Ltd.

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

Page 1 / 1 of Annex I

| Internal Number | Registration Number (at the German CA/ DIMDI) | Product Category (EDMS) | EDMS Code Description | Classification Annex |
|-----------------|--|----------------------------|------------------------------------|--------------------------|
| ASA-01 | DE/CA70/40838-155152 | 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 |

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Last update of the list: 2020-10-05
New products are marked in green / Obsolete products in red

| | | | | | | | | | |
|---------------------|---|--------------|---------------------------|----------------------------|-----------------------|-------------------------------------|---------------|--------------------------------|------------------------------|
| Internal Adm.-No.AR | Registration Number German CA: DE/CA70/40838... | Cataloge No. | Product name (Model name) | Indications (Intended use) | EDMA-Code [GMDN-Code] | EDMA-Description (Product category) | Applied Annex | Declaration of Conformity Date | CE-Mark (Notification at CA) |
| | | | | | 4 | | | | 5 |

To be filled by MTPC

| | | | | | | | | | |
|-----------|--------|------------------|----------------------------------|---|----------------|---------------------------------|----------------------|------------|------------|
| | | | | | | | | | |
| ASA-01 | 155152 | AM3471-K | Asan Easy Test® COVID-19 IgG/IgM | Asan Easy Test COVID-19 IgG/IgM Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. For professional use only. | 15 70 90 90 00 | Other Other Virology Rapid Test | Other IVD/ Annex III | 15.04.2020 | 23.04.2020 |
| ASA-02 | 157494 | AM-2414-K | Asan Easy Test® Influenza A/B | The Asan Easy Test® Influenza A/B is a chromatographic immunoassay kit for rapid, qualitative, and differential detection of influenza virus type A and type B (Not type C) infection from nasal or throat swab specimens. For professional use only. | 15 04 80 04 00 | Influenza & Para Influenza | Other IVD/ Annex III | 06.07.2020 | 10.08.2020 |
| ASA-03 | 157496 | 28355 (AM608-10) | ASAN Transport Medium (1) | Intended to collect, transport, and preserve oropharyngeal or nasopharyngeal mucosa for testing Viruses, Chlamydia, Mycoplasma, and Ureaplasma. | 14 01 02 20 00 | Transport Media (Tubes) | Other IVD/ Annex III | 06.07.2020 | 10.08.2020 |
| ASA-03-01 | 157496 | 28358 (AM608-10) | ASAN Transport Medium (II) | Intended to collect, transport, and preserve oropharyngeal or nasopharyngeal mucosa for testing Viruses, Chlamydia, Mycoplasma, and Ureaplasma. | 14 01 02 20 00 | Transport Media (Tubes) | Other IVD/ Annex III | 06.07.2020 | 10.08.2020 |


| Internal Adm.-No./AR | Registration Number German CA: DE/CA70/40838... | Catalogue No. | Product name (Model name) | Indications (Intended use) | EDMA-Code [Code] | EDMA-Description (Product category) | Applied Annex | Declaration of Conformity Date | CE-Mark (Notification at CA) |
|----------------------|---|----------------------|--|---|---------------------|--|-------------------------|--------------------------------|---------------------------------|
| ASA-04 | 158473 | AM3477-K AM3478-K | Product name: Novel Corona Virus Real Time PCR Detection Kit, Model name: Asan qPCR Test® COVID-19 | Asan qPCR Test® COVID-19 is a real-time reverse transcription polymerase chain reaction method from RNA extracted from sputum, nasopharyngeal swab, oropharyngeal swab, and bronchial alveolar lavage fluid in patients with suspected respiratory infections. It is a medical device for in vitro diagnosis that qualitatively detects genes (E gene and N gene) of new coronavirus (2019-nCoV) using Real-time RT-PCR. For professional use only. | 16 90 90 01 90 | Other Other Genetic Tests | Other IVD/ Annex III | 12.08.2020 | 02.10.2020 |

Remarks:

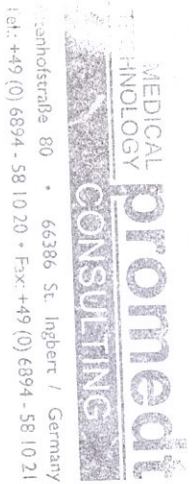
- All product, model or trade names have to be specified
- Please specify the intended use

Prepared: MT Promed Consulting GmbH

Released: Asan Pharmaceutical Co., Ltd

05.10.2020 

 12.10.2020



124-81-30401
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