



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

Sugentech Inc.
721-26 Jeongjungyeonje-ro Osong-eup,
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do 28161
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.

19 August 2021

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

**Sugentech Inc.**

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)	EDMS Code Description	Product Category (EDMS)	Classification Annex
SUG-01	DE/CA70/40838-145202	C-Reactive Protein	12 11 01 09 00	III
SUG-02	DE/CA70/40838-145203	Procalcitonin	12 06 90 16 00	III
SUG-03	DE/CA70/40838-150137	Manual I.A. Instruments/ Readers	22 03 01	III
SUG-04	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self-Testing
SUG-04-01	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self-Testing
SUG-04-02	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self-Testing
SUG-05	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self-Testing
SUG-05-01	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self-Testing
SUG-05-02	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self-Testing
SUG-05-03	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self-Testing
SUG-06	DE/CA70/40838-145679	LH – Rapid Test	12 70 05 04 00	Self-Testing
SUG-07	DE/CA70/40838-145205	Glycosylated/ Glycated Haemoglobin	12 06 01 06 00	III
SUG-08	DE/CA70/40838-145206	Troponin I/T – Rapid Test	12 70 13 03 00	III
SUG-09	DE/CA70/40838-154680	Other Other Clinical Instruments	26 09	III
SUG-10	DE/CA70/40838-161801	Influenza & Para Influenza	15 04 80 04 00	III
SUG-11	DE/CA70/40838-149025	Other Viral Antigen/ Antibody Detection	15 04 80 90 00	III
SUG-12	DE/CA70/40838-145211	β Human Chorionic Gonadotropin (incl. subunit)	12 05 02 06 00	III
SUG-13	DE/CA70/40838-145213	Immunoglobulin E - Total	12 02 01 02 00	III

**Sugentech Inc.**

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Internal Number	Registration Number (at the German CA/ DIMDI)	EDMS Code Description	Product Category (EDMS)	Classification Annex
SUG-14	DE/CA70/40838-148253	Mycobacterial Antigen Detection	15 01 07 01 00	III
SUG-15	DE/CA70/40838-163473	Specific Protein Controls	12 50 01 06 00	III
SUG-16	DE/CA70/40838-151366	Thyroid Stimulating Hormone	12 04 01 11 00	III
SUG-17	DE/CA70/40838-151955	Hormone Controls	12 50 01 04 00	III
SUG-18	DE/CA70/40838-151956	Cardiac Marker Controls	12 50 01 08 00	III
SUG-19	DE/CA70/40838-161800	Other Other Virology Rapid Tests	15 70 90 90 00	III
SUG-20	DE/CA70/40838-158846	Immunoglobulin E- Screenn	12 02 01 06 00	III
SUG-21	DE/CA70/40838-160749	Other Other Virology Reagents	15 04 90 90 00	III
SUG-22	DE/CA70/40838-162072	Automated I.A Systems	22 03 03	III
SUG-23	DE/CA70/40838-163410	Other Other Virology Rapid Tests	15 70 90 90 00	Self-Testing
SUG-23-01	DE/CA70/40838-163585	Other Other Virology Rapid Tests	15 70 90 90 00	Self-Testing
SUG-24	DE/CA/70/40838-163477	D-Dimer - Rapid Test	13 02 70 03 00	III
SUG-25	DE/CA/70/40838-165301	Semi-automated I.A. Systems	22 03 02	III

19 August 2021

Dr. Michael Rinck
- Managing Director -