



# 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.

05 November 2020

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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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<b>Internal Number</b>	<b>Registration Number</b> (at the German CA/ DIMDI)	<b>EDMS Code</b> <b>Description</b>	<b>Product Category</b> <b>(EDMS)</b>	<b>Classification</b> <b>Annex</b>
<b>SUG-01</b>	DE/CA70/40838-145202	C-Reactive Protein	12 11 01 09 00	III
<b>SUG-02</b>	DE/CA70/40838-145203	Procalcitonin	12 06 90 16 00	III
<b>SUG-03</b>	DE/CA70/40838-150137	Manual I.A. Instruments/ Readers	22 03 01	III
<b>SUG-04</b>	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self Testing
<b>SUG-04-01</b>	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self Testing
<b>SUG-04-02</b>	DE/CA70/40838-145677	Semi-automated I.A. Systems	22 03 02	Self Testing
<b>SUG-05</b>	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self Testing
<b>SUG-05-01</b>	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self Testing
<b>SUG-05-02</b>	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self Testing
<b>SUG-05-03</b>	DE/CA70/40838-145678	HCG – Rapid Test	12 70 05 02 00	Self Testing
<b>SUG-06</b>	DE/CA70/40838-145679	LH – Rapid Test	12 70 05 04 00	Self Testing
<b>SUG-07</b>	DE/CA70/40838-145202	Glycosylated/ Glycated Haemoglobin	12 06 01 06 00	III
<b>SUG-08</b>	DE/CA70/40838-145206	Troponin I/T – Rapid Test	12 70 13 03 00	III
<b>SUG-09</b>	DE/CA70/40838-154680	Other Other Clinical Instruments	26 09	III
<b>SUG-10</b>	DE/CA70/40838-145208	Influenza & Para Influenza	15 04 80 04 00	III
<b>SUG-11</b>	DE/CA70/40838-149025	Other Viral Antigen/ Antibody Detection	15 04 80 90 00	III
<b>SUG-12</b>	DE/CA70/40838-145211	β Human Chorionic Gonadotropin (incl. subunit)	12 05 02 06 00	III
<b>SUG-13</b>	DE/CA70/40838-145213	Immunoglobulin E - Total	12 02 01 02 00	III



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<b>SUG-14</b>	DE/CA70/40838-148253	Mycobacterial Antigen Detection	15 01 07 01 00	III
<b>SUG-15</b>	DE/CA70/40838-151958	Specific Protein Controls	12 50 01 06 00	III
<b>SUG-16</b>	DE/CA70/40838-151366	Thyroid Stimulating Hormone	12 04 01 11 00	III
<b>SUG-17</b>	DE/CA70/40838-151955	Hormone Controls	12 50 01 04 00	III
<b>SUG-18</b>	DE/CA70/40838-151956	Cardiac Marker Controls	12 50 01 08 00	III
<b>SUG-19</b>	DE/CA70/40838-158921	Other Other Virology Rapid Tests	15 70 90 90 00	III
<b>SUG-20</b>	DE/CA70/40838-158846	Immunoglobulin E- Screenn	12 02 01 06 00	III
<b>SUG-21</b>	DE/CA70/40838-158922	Other Other Virology Reagents	15 04 90 90 00	III

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