



# 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

**1Drop Inc.**  
**A-203, Keumkang Penterium IT Tower**  
**215, Galmachi-ro, Jungwon-gu,**  
**Gyeonggi-do, Seongnam-si**  
**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.

25 October 2021

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Dr. Michael Rinck  
- Managing Director -

**Enclosure**  
Annex I



### 1Drop Inc.

Annex I  
to "Certificate of EU Product Notification"  
(List of CE marked Products)

Internal Number	Registration Number (at the German CA/ DIMDI)	Product Category (EDMS)	EDMS Code Description	Classification Annex
<b>DRO-01</b>	DE/CA70/40838-151378	16 01 01 90 00	Other Monogenetic Disorders Test	III
<b>DRO-02</b>	DE/CA70/40838-156537	13 01 70 01 00	Haemoglobin (Hb)	III
<b>DRO-03</b>	DE/CA70/40838-156552	13 01 20 04 00	Haemoglobin Control	III
<b>DRO-04</b>	DE/CA70/40838-166610	27 02	Data Management Software/Consumables	III
<b>DRO-05</b>	DE/CA70/40838-151382	11 70 01 90 00	Other Blood Test Strips	III
<b>DRO-06</b>	DE/CA70/40838-156549	11 70 01 50 00	Calibrators and Controls (Blood Test Strips)	III
<b>DRO-07</b>	DE/CA70/40838-151385	11 70 01 01 00	Glucose Test Strips	III
<b>DRO-09</b>	DE/CA70/40838-151386	11 70 01 02 00	Cholesterol Test Strips	III
<b>DRO-10</b>	DE/CA70/40838-166606	16 90 90 01 90	Other Other Genetic Tests	III
<b>DRO-11</b>	DE/CA70/40838-155904	11 01 01 03 00	Alanine Amino-Transferase	III
<b>DRO-12</b>	DE/CA70/40838-156550	11 01 01 10 00	Aspartate Amino-Transferase	III
<b>DRO-13</b>	DE/CA70/40838-160967	15 04 40 90 00	Other Virology – NA Reagents	III
<b>DRO-14</b>	DE/CA70/40838-160968	15 04 40 04 00	Influenza & Para Influenza – NA Reagents	III
<b>DRO-15</b>	DE/CA70/40838-160969	15 04 40 05 00	Respiratory Syncytial Virus - NA Reagents	III
<b>DRO-16</b>	DE/CA70/40838-166608	24 09	Other Microbiology Instruments	III

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- Managing Director -