



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

Abon Biopharm (Hangzhou) Co., Ltd.
#198 12th Street East, Hangzhou
Economic & Technological Development
Hangzhou 310018
P. R. China

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.

2 December 2014

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

**Abon Biopharm (Hangzhou) 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
ABO-01	DE/CA70/40838/00128152	15 70 03 02 00	HIV 1 / 2 – Rapid Test	Annex II, List A
ABO-02	DE/CA70/40838/00128153	15 70 02 02 00	HCV Antibody - Rapid Test	Annex II, List A
ABO-03	DE/CA70/40838/00128154	15 70 02 01 00	HBsAg - Rapid Test	Annex II, List A
ABO-04	DE/CA70/40838/00130344	12 70 13 04 00	Brain Natriuric Peptide - Rapid Test	Annex III
ABO-05	DE/CA70/40838/00130345	12 70 11 01 00	C-Reactive Protein - Rapid Test	Annex III
ABO-06	DE/CA70/40838/00130346	12 70 13 01 00	CK - MB / Myoglobin - Rapid Test	Annex III
ABO-07	DE/CA70/40838/00130349	12 70 13 03 00	Troponin I/T - Rapid Test	Annex III
ABO-08	DE/CA70/40838/00130350	12 70 13 02 00	Myoglobin - Rapid Test	Annex III
ABO-09	DE/CA70/40838/00130351	15 70 01 02 00	H. Pylori - Rapid Test	Annex III
ABO-10	DE/CA70/40838/00130352	12 03 90 01 00	Alphafetoprotein	Annex III
ABO-11	DE/CA70/40838/00130353	12 03 01 31 00	Carcinoembryonic Antigen	Annex III
ABO-12	DE/CA70/40838/00130354	15 04 80 01 00	Adenovirus	Annex III
ABO-13	DE/CA70/40838/00130355	15 04 80 06 00	Rotavirus	Annex III
ABO-14	DE/CA70/40838/00130356	15 70 01 90 00	Other Bacteriology Rapid Tests	Annex III
ABO-15	DE/CA70/40838/00130361	12 70 05 02 00	HCG - Rapid Test	Annex III
ABO-16	DE/CA70/40838/00130808	12 70 05 02 00	HCG - Rapid Test	Self-testing
ABO-17	DE/CA70/40838/00130732	12 70 09 01 00	Amphetamines Group - Rapid Test	Annex III
ABO-18	DE/CA70/40838/00130733	12 70 09 07 00	Methadone - Rapid Test	Annex III
ABO-19	DE/CA70/40838/00130734	12 70 09 08 00	Opiates - Rapid Test	Annex III
ABO-20	DE/CA70/40838/00130735	12 70 09 09 00	Phencyclidine - Rapid Test	Annex III
ABO-21	DE/CA70/40838/00130736	12 70 09 10 00	Tricyclic Antidepressants - Rapid Test	Annex III
ABO-22	DE/CA70/40838/00130747	12 70 09 03 00	Barbiturates - Rapid Test	Annex III
ABO-23	DE/CA70/40838/00130748	12 70 09 06 00	Cocaine + Cocaine Metabolites - Rapid Test	Annex III
ABO-24	DE/CA70/40838/00130753	12 70 09 05 00	Cannabinoids - Rapid Test	Annex III



Internal Number	Registration Number (at the German CA/ DIMDI)	Product Category (EDMS)	EDMS Code Description	Classification Annex
ABO-25	DE/CA70/40838/00130757	12 70 09 04 00	Benzodiazepines - Rapid Test	Annex III
ABO-26	DE/CA70/40838/00130791	12 09 01 02 00	Amphetamine/ Methamphetamine Specific (+Ecstasy) - Rapid Test	Annex III
ABO-27	DE/CA70/40838/00130836	12 70 09 90 00	Other Drugs of Abuse/Toxicology Rapid Tests	Annex III
ABO-28	DE/CA70/40838/00130837	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Tests	Annex III
ABO-29	DE/CA70/40838/00130801	12 70 05 01 00	FSH-Rapid Test	Annex III
ABO-30	DE/CA70/40838/00130803	12 70 05 01 00	FSH-Rapid Test	Self-testing
ABO-31	DE/CA70/40838/00131230	15 01 04 01 00	H. Pylori Antigen Detection	Annex III
ABO-32	DE/CA70/40838/00131231	15 70 01 03 00	Strep A- Rapid Test	Annex III
ABO-33	DE/CA70/40838/00131232	15 70 01 05 00	Syphilis-Rapid Test	Annex III
ABO-34	DE/CA70/40838/00131233	12 03 90 04 00	Fecal Occult Blood (IC)	Annex III
ABO-35	DE/CA70/40838/00132011	15 04 80 04 00	Influenza & Para Influenza	Annex III
ABO-36	DE/CA70/40838/00131234	15 70 90 03 00	Mononucleosis - Rapid Test	Annex III
ABO-37	DE/CA70/40838/00132012	14 05 02 02 00	Plasmodium falciparum	Annex III
ABO-38	DE/CA70/40838/00131235	12 70 05 04 00	LH - Rapid Test	Annex III
ABO-39	DE/CA70/40838/00131252	12 70 05 04 00	LH - Rapid Test	Self-testing
ABO-40	DE/CA70/40838/00131255	15 01 01 01 00	Chlamydia Antigen Detection	II, List B
ABO-41	DE/CA70/40838/00131256	12 70 03 11 00	PSA - Rapid Test	II, List B
ABO-42	DE/CA70/40838/00131269	15 04 02 06 00	CMV IgM	II, List B
ABO-43	DE/CA70/40838/00131270	15 04 01 06 00	Rubella Virus IgM	II, List B
ABO-44	DE/CA70/40838/00131267	15 04 03 06 00	HSV IgM	Annex III
ABO-45	DE/CA70/40838/00131271	15 05 01 06 00	Toxoplasma Antibody IgM	II, List B
ABO-46	DE/CA70/40838/00131272	15 04 03 06 00	HSV IgM	II, List B

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Dr. Michael Rinck
- Managing Director -