

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

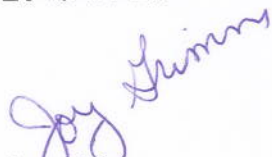
AccuBioTech Co., Ltd.
Building 10, No.28, Yuhua Road
101300 Beijing
CHINA

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated April 23, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2019-04-23


Joy Grimm
Senior Consultant
MDSS GmbH

Annex A dated April 23, 2019:
Manufacturer: AccuBioTech Co., Ltd.

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
-	Accu-Tell® Urine Reagent Test Strips	-	11 70 02 02 00	Urine Multi-constituent Test Strips	"Other"	N/A	DE/CA09/0170/A06/IVD/003-01
-	Accu-Tell® Rapid FOB Test	-	12 03 90 04	Faecal Occult Blood (IC)	"Other"	N/A	DE/CA09/0170/A06/IVD/006-01
ABT-CT-B59	Accu-Tell® Rapid Troponin I Test	Whole Blood / Serum / Plasma	12 13 01 07 00	Troponin I/T	"Other"	N/A	DE/CA09/0170/A06/IVD/002
ABT-FT-A1, ABT-FT-B1, ABT-FT-C1	Accu-Tell® One Step HCG Pregnancy Test	Model: Strip, Cassette, Midstream	12 70 05 02	HCG - RT & POC	Self Test	0197 / HL 60093883 0001 15.07.2019	DE/CA09/0170/A06/IVD/009
-	Accu-Tell® One Step HCG Urine/Serum Test	-	12 70 05 02	HCG - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/008-01
ABT-DOA-B24	Accu-Tell® AMP Test	Model: Strip, Cassette	12 70 09 01	Amphetamines - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/024
ABT-DOA-B55	Accu-Tell® MDMA Test	Model: Strip, Cassette	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/025
ABT-DOA-B28	Accu-Tell® BAR Test	Model: Strip, Cassette	12 70 09 03	Barbiturates - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/023
ABT-DOA-B29	Accu-Tell® BZO Test	Model: Strip, Cassette	12 70 09 04	Benzodiazepines - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/021
ABT-DOA-B23	Accu-Tell® COC Test	Model: Strip, Cassette	12 70 09 06	Cocaine + Cocaine Metabolites - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/020
ABT-DOA-B35	Accu-Tell® PCP Test	Model: Strip, Cassette	12 70 09 09	Phencyclidine - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/030
-	Accu-Tell® One Step Multi-10 Drug of Abuse Test	-	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA-B144	Accu-Tell® Rapid Multi-4 Drug Test	Model: Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA-E31	Accu-Tell® Rapid Multi-5 Drug Test	Model: Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA-E32	Accu-Tell® Rapid Multi-6 Drug Test	Model: Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA--G126	Accu-Tell® Multi-6 Drug Cup (Urine)	Model: Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA--G127	Accu-Tell® Multi-7 Drug Cup (Urine)	Model: Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA--G128	Accu-Tell® Multi-8 Drug Cup (Urine)	Model: Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA--G129	Accu-Tell® Multi-9 Drug Cup (Urine)	Model: Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA--G130	Accu-Tell® Multi-10 Drug Cup (Urine)	Model: Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/007-03
ABT-DOA-B26	Accu-Tell® MOP Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01

Annex A dated April 23, 2019:
Manufacturer: AccuBioTech Co., Ltd.

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-B102	Accu-Tell® KET Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-B141	Accu-Tell® COT Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-B140	Accu-Tell® BUP Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-B164	Accu-Tell® TML Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-B54	Accu-Tell® TCA Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-A162	Accu-Tell® OXY Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT-DOA-B159	Accu-Tell® FYL Test	Model: Strip, Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/022-01
ABT- CT-B251	Accu-Tell® CRP Semi-Quantitative Test	Model: Strip, Cassette	12 70 11 01	C-Reactive Protein - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/026
ABT-CT-B66	Accu-Tell® CK-MB Test	Model: Strip, Cassette	12 70 13 01	Creatine Kinase - MB mass - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/019-01
ABT- CT-B68	Accu-Tell® Myoglobin Test	Model: Strip, Cassette	12 70 13 02	Myoglobin - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/029
ABT- CT-B111	Accu-Tell® NT-proBNP Test	Model: Strip, Cassette	12 70 13 04	BNP / proBNP - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/027
ABT-CT-E71	Accu-Tell® Myoglobin/CK-MB/Troponin I Test	Model: Strip, Cassette	12 70 13 70	Multiple Cardiac Markers - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/028
ABT-IDT-B266	Accu-Tell® PCT Semi-Quantitative Test	Model: Strip, Cassette	12 70 90 90	Other other Rapid Tests & Point of Care Immunohistochemistry	"Other"	N/A	DE/CA09/0170/A06/IVD/017-01
ABT-CT-B110	Accu-Tell® Rapid D-Dimer Test	Model: Strip, Cassette	13 02 70 03	D-Dimer - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/018-01
-	Accu-Tell® Rapid H. pylori Antigen Test	-	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/005-02
ABT-IDT-A13, ABT-ICT-B13	Accu-Tell® Rapid H. pylori Antibody Test	Model: Strip, Cassette	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/005-02
-	Accu-Tell® Rapid Strep A Test	-	15 70 01 03 00	Strep A - Rapid Test	"Other"	N/A	DE/CA09/0170/A06/IVD/001
-	Accu-Tell® Rapid Syphilis Test	Model: Strip, Cassette	15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/012
ABT-IDT-B314	ACCU-TELL® Clostridium difficile Toxin A+ Toxin B Combo Test	Model: Strip, Cassette	15 70 01 06	Clostr. diff. incl Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/016-01
ABT-IDT-B315	ACCU-TELL® Clostridium difficile GDH Test	Model: Strip, Cassette	15 70 01 06	Clostr. diff. incl Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/016-01

Annex A dated April 23, 2019:
Manufacturer: AccuBioTech Co., Ltd.

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-IDT-B316	ACCU-TELL® Clostridium difficile GDH+ Toxin A +Toxin B Combo Test	Model: Strip, Cassette	15 70 01 06	Clostr. diff. incl Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/016-01
-	Accu-Tell® Rapid Typhoid Test	-	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/004-02
ABT-IDT-B57	Accu-Tell® Rapid Tuberculosis Test	Model: Cassette	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/004-02
ABT-IDT-B218	Accu-Tell® HAV IgM Test	Model: Strip, Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/032
ABT-IDT-B226	Accu-Tell® Hav IgM/IgG Test	Model: Strip, Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/032
ABT-IDT-B99	Accu-Tell® Rapid Malaria P.f. /Pan Test	Model: Strip, Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/013-01
ABT-IDT-B58	Accu-Tell® Rapid Malaria P.f. /P.v. Test	Model: Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/013-01
ABT-IDT-B236	Accu-Tell® Rapid Malaria P.f. /P.v./Pan Test	Model: Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/013-01
ABT-IDT-B219	Accu-Tell® Chagas Test	Model: Strip, Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/031-01
ABT-IDT-B255	Accu-Tell® Giardia lamblia Test	Model: Strip, Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/031-01
ABT-IDT-B292	Accu-Tell® Entamoeba histolytica Test	Model: Strip, Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/031-01
ABT-IDT-B247	Accu-Tell® Influenza A+B Test	Model: Strip, Cassette	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/0170/A06/IVD/033
-	Accu-Tell® Rapid Dengue IgG/IgM/NS1 Test	-	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/011-01
ABT-IDT-B97	Accu-Tell® Rapid Dengue IgG/IgM Test	Model: Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/011-01
ABT-IDT-B216	Accu-Tell® Rapid Dengue NS1 Test	Model: Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/011-01
-	Accu-Tell® Rapid Chikungunya IgG/IgM Test	-	15 70 90 90	Other Other Virology Rapid Tests	"Other"	N/A	DE/CA09/0170/A06/IVD/010-02
ABT-IDT-B63	Accu-Tell® Rotavirus Test	Model: Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/010-02
ABT-IDT-B64	Accu-Tell® Rotavirus/Adenovirus Test	Model: Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/0170/A06/IVD/010-02

