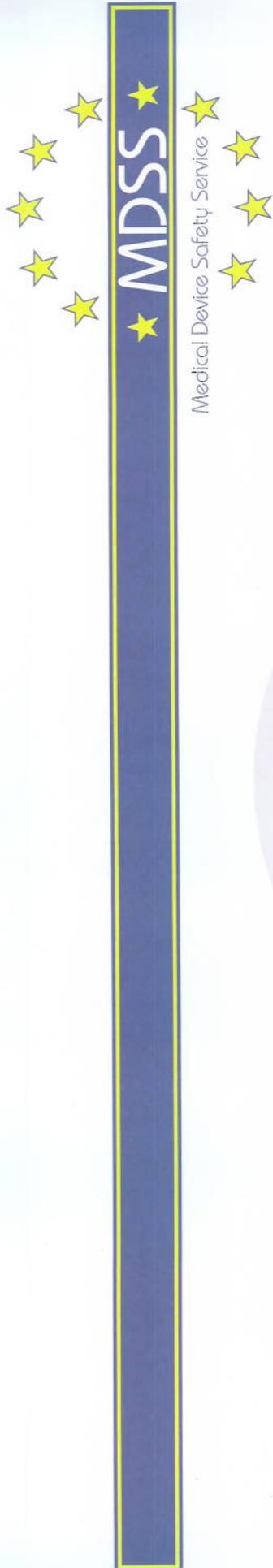


# Certificate of CE-Registration



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

A handwritten signature in blue ink, which appears to read 'Joy Grimm', is written over the printed name.

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 Immunohemistry	"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
ABT-IDT-A13, ABT-ICT-B13	Accu-Tell® Rapid H. pylori Antigen 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 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	Model: Strip, Cassette	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