



MDSS

Medical Device Safety Service

# 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 4, Maohua Industry Park, No. 1,  
CAIDA Third Street, Nancai Town, Shunyi District,  
101399 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 2022-07-26**

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.

2022-07-26



Dr. Patrick Pille  
Consultant  
MDSS GmbH

| 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               | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A36             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A42             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A252            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A253            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A243            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A37             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A38             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A334            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A39             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A40             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A41             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A34             | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A380            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-UM-A381            | Accu-Tell® Urine Reagent Strips                    | Strip                             | 11 70 02 02        | Urine Multi-constituent Test Strips (manual) | "Other"         | N/A                                  | DE/CA09/00035534           |
| ABT-INF-B299           | Accu-Tell® Calprotectin Semi-Quantitative Cassette | Cassette                          | 12 01 90 10        | Calprotectin                                 | "Other"         | N/A                                  | DE/CA09/00103912           |
| ABT-FOB-A22            | Accu-Tell® FOB Strip                               | Cassette                          | 12 03 90 04        | Faecal Occult Blood (IC)                     | "Other"         | N/A                                  | DE/CA09/00087395           |
| ABT-FOB-B22            | Accu-Tell® Rapid FOB Test                          | Cassette                          | 12 03 90 04        | Faecal Occult Blood (IC)                     | "Other"         | N/A                                  | DE/CA09/00087395           |
| ABT-CT-B59             | Accu-Tell® Rapid Troponin I Test                   | Cassette                          | 12 13 01 07        | Troponin I/T                                 | "Other"         | N/A                                  | DE/CA09/00086198           |
| ABT-FT-A2              | Accu-Tell® One Step HCG Urine/Serum Test           | Strip                             | 12 70 05 02        | HCG - RT & 2OC                               | "Other"         | N/A                                  | DE/CA09/00087392           |
| ABT-FT-B2              | Accu-Tell® One Step HCG Urine/Serum Test           | Cassette                          | 12 70 05 02        | HCG - RT & 2OC                               | "Other"         | N/A                                  | DE/CA09/00087392           |
| ABT-FT-A387            | Accu-Tell® HCG Multi-Line Strip (Urine)            | Strip                             | 12 70 05 02        | HCG - RT & 2OC                               | "Other"         | N/A                                  | DE/CA09/00087392           |

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| ABT-FT-C387            | Accu-Tell® HCG Multi-Line Midstream (Urine)  | Midstream                         | 12 70 05 02        | HCG - RT & POC                                             | "Other"         | N/A                                  | DE/CA09/00087392           |
| ABT-FT-A1              | Accu-Tell® One Step HCG Pregnancy Test       | Strip                             | 12 70 05 02        | HCG - RT & POC                                             | Self Test       | 0197/HL<br>2187098-1                 | DE/CA09/00087391           |
| ABT-FT-B1              | Accu-Tell® One Step HCG Pregnancy Test       | Cassette                          | 12 70 05 02        | HCG - RT & POC                                             | Self Test       | 2024-05-26<br>0197/HL<br>2187098-1   | DE/CA09/00087391           |
| ABT-FT-C1              | Accu-Tell® One Step HCG Pregnancy Test       | Midstream                         | 12 70 05 02        | HCG - RT & POC                                             | Self Test       | 2024-05-26<br>0197/HL<br>2187098-1   | DE/CA09/00087391           |
| ABT-DOA-A24            | Accu-Tell® AMP Test                          | Strip                             | 12 70 09 01        | Amphetamines - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091639           |
| ABT-DOA-B24            | Accu-Tell® AMP Test                          | Cassette                          | 12 70 09 01        | Amphetamines - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091639           |
| ABT-DOA-B46            | Accu-Tell® AMP Cassette                      | Cassette                          | 12 70 09 01        | Amphetamines - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091639           |
| ABT-DOA-A55            | Accu-Tell® MDMA Test                         | Strip                             | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-B55            | Accu-Tell® MDMA Test                         | Cassette                          | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-A25            | Accu-Tell® MET Test                          | Strip                             | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-B25            | Accu-Tell® MET Test                          | Cassette                          | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-B69            | Accu-Tell® MET Cassette                      | Cassette                          | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-B87            | Accu-Tell® MDMA Cassette                     | Cassette                          | 12 70 09 02        | Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC | Other           | N/A                                  | DE/CA09/00091638           |
| ABT-DOA-A28            | Accu-Tell® BAR Test                          | Strip                             | 12 70 09 03        | Barbiturates - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091640           |
| ABT-DOA-B28            | Accu-Tell® BAR Test                          | Cassette                          | 12 70 09 03        | Barbiturates - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091640           |
| ABT-DOA-B103           | Accu-Tell® BAR Cassette                      | Cassette                          | 12 70 09 03        | Barbiturates - RT & POC                                    | Other           | N/A                                  | DE/CA09/00091640           |
| ABT-DOA-A29            | Accu-Tell® BZO Test                          | Strip                             | 12 70 09 04        | Benzodiazepines - RT & POC                                 | Other           | N/A                                  | DE/CA09/00091642           |
| ABT-DOA-B29            | Accu-Tell® BZO Test                          | Cassette                          | 12 70 09 04        | Benzodiazepines - RT & POC                                 | Other           | N/A                                  | DE/CA09/00091642           |
| ABT-DOA-B70            | Accu-Tell® BZO Cassette                      | Cassette                          | 12 70 09 04        | Benzodiazepines - RT & POC                                 | Other           | N/A                                  | DE/CA09/00091642           |
| ABT-DOA-A165           | Accu-Tell® Synthetic Marijuana (K2) Test     | Strip                             | 12 70 09 05        | Cannabinoids - RT & POC                                    | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-B165           | Accu-Tell® Synthetic Marijuana (K2) Test     | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                                    | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-B240           | Accu-Tell® Synthetic Marijuana (K2) Cassette | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                                    | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-A27            | Accu-Tell® THC Test                          | Strip                             | 12 70 09 05        | Cannabinoids - RT & POC                                    | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-B27            | Accu-Tell® THC Test                          | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                                    | Other           | N/A                                  | DE/CA09/00102773           |

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**Manufacturer: AccuBioTech Co., Ltd.**

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| ABT-DOA-B67            | Accu-Tell® THC Cassette                                  | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                     | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-A267           | Accu-Tell® Synthetic Marijuana K2 + (AB-Pinaca) Strip    | Strip                             | 12 70 09 05        | Cannabinoids - RT & POC                     | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-B267           | Accu-Tell® Synthetic Marijuana K2 + (AB-Pinaca) Cassette | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                     | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-B392           | Accu-Tell® THC Cassette (Saliva)                         | Cassette                          | 12 70 09 05        | Cannabinoids - RT & POC                     | Other           | N/A                                  | DE/CA09/00102773           |
| ABT-DOA-A23            | Accu-Tell® COC Test                                      | Strip                             | 12 70 09 06        | Cocaine + Cocaine Metabolites - RT & POC    | Other           | N/A                                  | DE/CA09/00091643           |
| ABT-DOA-B23            | Accu-Tell® COC Test                                      | Cassette                          | 12 70 09 06        | Cocaine + Cocaine Metabolites - RT & POC    | Other           | N/A                                  | DE/CA09/00091643           |
| ABT-DOA-B48            | Accu-Tell® COC Cassette                                  | Cassette                          | 12 70 09 06        | Cocaine + Cocaine Metabolites - RT & POC    | Other           | N/A                                  | DE/CA09/00091643           |
| ABT-DOA-A30            | Accu-Tell® MTD Test                                      | Strip                             | 12 70 09 07        | Methadone incl. EDDP - RT & POC             | Other           | N/A                                  | DE/CA09/00103061           |
| ABT-DOA-B30            | Accu-Tell® MTD Test                                      | Cassette                          | 12 70 09 07        | Methadone incl. EDDP - RT & POC             | Other           | N/A                                  | DE/CA09/00103061           |
| ABT-DOA-B172           | Accu-Tell® MTD Cassette                                  | Cassette                          | 12 70 09 07        | Methadone incl. EDDP - RT & POC             | Other           | N/A                                  | DE/CA09/00103061           |
| ABT-DOA-A26            | Accu-Tell® MOP Test                                      | Strip                             | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-B26            | Accu-Tell® MOP Test                                      | Cassette                          | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-A161           | Accu-Tell® OPI Test                                      | Strip                             | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-B161           | Accu-Tell® OPI Test                                      | Cassette                          | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-B47            | Accu-Tell® MOP Cassette                                  | Cassette                          | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-B244           | Accu-Tell® OPI Cassette                                  | Cassette                          | 12 70 09 08        | Opiates - RT & POC                          | Other           | N/A                                  | DE/CA09/00093542           |
| ABT-DOA-B173           | Accu-Tell® PCP Cassette                                  | Cassette                          | 12 70 09 09        | Phencyclidine - RT & POC                    | Other           | N/A                                  | DE/CA09/00091862           |
| ABT-DOA-A35            | Accu-Tell® PCP Test                                      | Strip                             | 12 70 09 09        | Phencyclidine - RT & POC                    | Other           | N/A                                  | DE/CA09/00091862           |
| ABT-DOA-B35            | Accu-Tell® PCP Test                                      | Cassette                          | 12 70 09 09        | Phencyclidine - RT & POC                    | Other           | N/A                                  | DE/CA09/00091862           |
| ABT-DOA-A54            | Accu-Tell® TCA Test                                      | Strip                             | 12 70 09 10        | Tricyclic Antidepressants - RT & POC        | Other           | N/A                                  | DE/CA09/00093543           |
| ABT-DOA-B54            | Accu-Tell® TCA Test                                      | Cassette                          | 12 70 09 10        | Tricyclic Antidepressants - RT & POC        | Other           | N/A                                  | DE/CA09/00093543           |
| ABT-DOA-G130           | Accu-Tell® Multi-10 Drug Cup (Urine)                     | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G127           | Accu-Tell® Multi-7 Drug Cup (Urine)                      | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G128           | Accu-Tell® Multi-8 Drug Cup (Urine)                      | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G129           | Accu-Tell® Multi-9 Drug Cup (Urine)                      | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| -                      | Accu-Tell® One Step Multi-10 Drug of Abuse Test          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B144           | Accu-Tell® Rapid Multi-4 Drug Test                       | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E31            | Accu-Tell® Rapid Multi-5 Drug Test                       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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| ABT-DOA-E32            | Accu-Tell® Rapid Multi-6 Drug Test             | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G126           | Accu-Tell® Multi-6 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H130           | Accu-Tell® Multi-10 Drug Cup W/Lock (Urine)    | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA- B351          | Accu-Tell® Multi-Line 12 Drug Cassette (Urine) | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E73            | Accu-Tell® Multi-7 Drug Panel                  | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E51            | Accu-Tell® Multi-2 Drug Panel (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E44            | Accu-Tell® Multi-3 Drug Panel (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E45            | Accu-Tell® Multi-4 Drug Panel (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E74            | Accu-Tell® Multi-8 Drug Panel (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E75            | Accu-Tell® Multi-9 Drug Panel (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E319           | Accu-Tell® Multi-11 Drug Panel (Urine)         | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-E320           | Accu-Tell® Multi-12 Drug Panel (Urine)         | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D282           | Accu-Tell® Multi-2 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D283           | Accu-Tell® Multi-3 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D284           | Accu-Tell® Multi-4 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D285           | Accu-Tell® Multi-5 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D286           | Accu-Tell® Multi-6 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D287           | Accu-Tell® Multi-7 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D288           | Accu-Tell® Multi-8 Drug Dip Card (Urine)       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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| ABT-DOA-D289           | Accu-Tell® Multi-9 Drug Dip Card (Urine)                        | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D290           | Accu-Tell® Multi-10 Drug Dip Card (Urine)                       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D355           | Accu-Tell® Multi-11 Drug Dip Card (Urine)                       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-D356           | Accu-Tell® Multi-12 Drug Dip Card (Urine)                       | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B112           | Accu-Tell® Multi-2 Drug Cassette (Urine)                        | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B113           | Accu-Tell® Multi-3 Drug Cassette (Urine)                        | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B114           | Accu-Tell® Multi-4 Drug Cassette (Urine)                        | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B115           | Accu-Tell® Multi-5 Drug Cassette (Urine)                        | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B116           | Accu-Tell® Multi-Line 6 Drug Cassette (Urine)                   | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B117           | Accu-Tell® Multi-Line 7 Drug Cassette (Urine)                   | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B118           | Accu-Tell® Multi-Line 8 Drug Cassette (Urine)                   | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B119           | Accu-Tell® Multi-Line 9 Drug Cassette (Urine)                   | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B120           | Accu-Tell® Multi-Line 10 Drug Cassette (Urine)                  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B350           | Accu-Tell® Multi-Line 11 Drug Cassette (Urine)                  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M122           | Accu-Tell® Multi-2 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M123           | Accu-Tell® Multi-3 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M124           | Accu-Tell® Multi-4 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M125           | Accu-Tell® Multi-5 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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| 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-M125           | Accu-Tell® Multi-Line 5 Drug Cup W/Lock & Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M126           | Accu-Tell® Multi-Line 6 Drug Cup W/Lock & Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M127           | Accu-Tell® Multi-Line 7 Drug Cup W/Lock & Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M128           | Accu-Tell® Multi-Line 8 Drug Cup W/Lock & Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M129           | Accu-Tell® Multi-Line 9 Drug Cup W/Lock & Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M130           | Accu-Tell® Multi-Line 10 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M131           | Accu-Tell® Multi-Line 11 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-M132           | Accu-Tell® Multi-Line 12 Drug Cup W/Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H122           | Accu-Tell® Multi-2 Drug Cup W/Lock (Urine)                            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H123           | Accu-Tell® Multi-3 Drug Cup W/Lock (Urine)                            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H124           | Accu-Tell® Multi-4 Drug Cup W/Lock (Urine)                            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H125           | Accu-Tell® Multi-5 Drug Cup W/Lock (Urine)                            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H126           | Accu-Tell® Multi-6 Drug Cup W/Lock (Urine)                            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H127           | Accu-Tell® Multi-Line 7 Drug Cup W/Lock (Urine)                       | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H128           | Accu-Tell® Multi-Line 8 Drug Cup W/Lock (Urine)                       | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H129           | Accu-Tell® Multi-Line 9 Drug Cup W/Lock (Urine)                       | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H131           | Accu-Tell® Multi-Line 11 Drug Cup W/Lock (Urine)                      | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-H132           | Accu-Tell® Multi-Line 12 Drug Cup W/Lock (Urine)                      | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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**Annex A: 2022-07-26**  
**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-L122           | Accu-Tell® Multi-2 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L123           | Accu-Tell® Multi-3 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L124           | Accu-Tell® Multi-4 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L125           | Accu-Tell® Multi-5 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L126           | Accu-Tell® Multi-6 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L127           | Accu-Tell® Multi-7 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L128           | Accu-Tell® Multi-8 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L129           | Accu-Tell® Multi-9 Drug Cup W/Adulteration Strip (Urine)  | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L130           | Accu-Tell® Multi-10 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L131           | Accu-Tell® Multi-11 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L132           | Accu-Tell® Multi-12 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L133           | Accu-Tell® Multi-13 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L134           | Accu-Tell® Multi-14 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L135           | Accu-Tell® Multi-15 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L136           | Accu-Tell® Multi-16 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-L137           | Accu-Tell® Multi-17 Drug Cup W/Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G122           | Accu-Tell® Multi-2 Drug Cup (Urine)                       | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G123           | Accu-Tell® Multi-3 Drug Cup (Urine)                       | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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**Annex A: 2022-07-26**  
**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-G124           | Accu-Tell® Multi-4 Drug Cup (Urine)             | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G125           | Accu-Tell® Multi-5 Drug Cup (Urine)             | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G131           | Accu-Tell® Multi-11 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G132           | Accu-Tell® Multi-12 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G133           | Accu-Tell® Multi-13 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G134           | Accu-Tell® Multi-14 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G135           | Accu-Tell® Multi-15 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G136           | Accu-Tell® Multi-16 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G137           | Accu-Tell® Multi-17 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-G138           | Accu-Tell® Multi-18 Drug Cup (Urine)            | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B142           | Accu-Tell® Multi-2 Drug Cassette (Saliva)       | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B143           | Accu-Tell® Multi-3 Drug Cassette (Saliva)       | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B145           | Accu-Tell® Multi-5 Drug Cassette (Saliva)       | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B146           | Accu-Tell® Multi-Line 6 Drug Cassette (Saliva)  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B147           | Accu-Tell® Multi-Line 7 Drug Cassette (Saliva)  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B148           | Accu-Tell® Multi-Line 8 Drug Cassette (Saliva)  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B149           | Accu-Tell® Multi-Line 9 Drug Cassette (Saliva)  | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B150           | Accu-Tell® Multi-Line 10 Drug Cassette (Saliva) | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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**Annex A: 2022-07-26**  
**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-B388           | Accu-Tell® Multi-Line 1.1 Drug Cassette (Saliva)           | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-B389           | Accu-Tell® Multi-Line 1.2 Drug Cassette (Saliva)           | Cassette                          | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N340           | Accu-Tell® Multi-2 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N341           | Accu-Tell® Multi-3 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N342           | Accu-Tell® Multi-4 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N343           | Accu-Tell® Multi-5 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N344           | Accu-Tell® Multi-6 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N345           | Accu-Tell® Multi-7 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N346           | Accu-Tell® Multi-8 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N347           | Accu-Tell® Multi-9 Drug Cup W/Indicator (Saliva)           | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N348           | Accu-Tell® Multi-10 Drug Cup W/Indicator (Saliva)          | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N390           | Accu-Tell® Multi-11 Drug Cup W/Indicator (Saliva)          | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-N391           | Accu-Tell® Multi-12 Drug Cup W/Indicator (Saliva)          | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K340           | Accu-Tell® Multi-2 Drug Cup W/Indicator & Alcohol (Saliva) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K341           | Accu-Tell® Multi-3 Drug Cup W/Indicator & Alcohol (Saliva) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K342           | Accu-Tell® Multi-4 Drug Cup W/Indicator & Alcohol (Saliva) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K343           | Accu-Tell® Multi-5 Drug Cup W/Indicator & Alcohol (Saliva) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K344           | Accu-Tell® Multi-6 Drug Cup W/Indicator & Alcohol (Saliva) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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| 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-K345           | Accu-Tell® Multi-7 Drug Cup W/Indicator & Alcohol (Saliva)                     | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K346           | Accu-Tell® Multi-8 Drug Cup W/Indicator & Alcohol (Saliva)                     | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K347           | Accu-Tell® Multi-9 Drug Cup W/Indicator & Alcohol (Saliva)                     | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K348           | Accu-Tell® Multi-10 Drug Cup W/Indicator & Alcohol (Saliva)                    | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-K390           | Accu-Tell® Multi-11 Drug Cup W/Indicator & Alcohol (Saliva)                    | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O51            | Accu-Tell® Multi-2 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O44            | Accu-Tell® Multi-3 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O45            | Accu-Tell® Multi-4 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O31            | Accu-Tell® Multi-5 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O32            | Accu-Tell® Multi-6 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O73            | Accu-Tell® Multi-7 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O74            | Accu-Tell® Multi-8 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O75            | Accu-Tell® Multi-9 Drug Panel W/Alcohol & Adulteration Strip (Urine)           | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-O53            | Accu-Tell® Multi-10 Drug Panel W/Alcohol & Adulteration Strip (Urine)          | Panel                             | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P122           | Accu-Tell® Multi-Line 2 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P123           | Accu-Tell® Multi-Line 3 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P124           | Accu-Tell® Multi-Line 4 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P125           | Accu-Tell® Multi-Line 5 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                               | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

| REF, UDI, Model Number | Notified Device Names                                                          | Additional Information | Notified EDMA Code | Notified EDMA Description                   | Notified Class. | Notified EC Certificate No. & Expiry | German Registration Number |
|------------------------|--------------------------------------------------------------------------------|------------------------|--------------------|---------------------------------------------|-----------------|--------------------------------------|----------------------------|
| ABT-DOA-P126           | Accu-Tell® Multi-Line 6 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P127           | Accu-Tell® Multi-Line 7 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-P128           | Accu-Tell® Multi-Line 8 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine) | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q122           | Accu-Tell® Multi-2 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q123           | Accu-Tell® Multi-3 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q124           | Accu-Tell® Multi-4 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q125           | Accu-Tell® Multi-5 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q126           | Accu-Tell® Multi-6 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q127           | Accu-Tell® Multi-7 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q128           | Accu-Tell® Multi-8 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q129           | Accu-Tell® Multi-9 Drug Cup W/Alcohol & Adulteration Strip (Urine)             | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q130           | Accu-Tell® Multi-10 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q131           | Accu-Tell® Multi-11 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q132           | Accu-Tell® Multi-12 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q133           | Accu-Tell® Multi-13 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q134           | Accu-Tell® Multi-14 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q135           | Accu-Tell® Multi-15 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-Q136           | Accu-Tell® Multi-16 Drug Cup W/Alcohol & Adulteration Strip (Urine)            | Cup                    | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |

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**Annex A: 2022-07-26**  
**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-C144           | Accu-Tell® Multi-Line 4 Drug Device (Saliva) | Device                            | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-C145           | Accu-Tell® Multi-Line 5 Drug Device (Saliva) | Device                            | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-C146           | Accu-Tell® Multi-Line 6 Drug Device (Saliva) | Device                            | 12 70 09 70        | Multiple Drugs of Abuse/Toxicology RT & POC | "Other"         | N/A                                  | DE/CA09/00087393           |
| ABT-DOA-A140           | Accu-Tell® BUP Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B140           | Accu-Tell® BUP Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A141           | Accu-Tell® COT Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B141           | Accu-Tell® COT Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A170           | Accu-Tell® Ethyl Glucoronide (ETG) Test      | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B170           | Accu-Tell® Ethyl Glucoronide (ETG) Test      | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A159           | Accu-Tell® FYL Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B159           | Accu-Tell® FYL Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A102           | Accu-Tell® KET Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B102           | Accu-Tell® KET Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A162           | Accu-Tell® OXY Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B162           | Accu-Tell® OXY Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-A164           | Accu-Tell® TML Test                          | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B164           | Accu-Tell® TML Test                          | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | Other           | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B104           | Accu-Tell® BUP Cassette                      | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | "Other"         | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B175           | Accu-Tell® COT Cassette                      | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | "Other"         | N/A                                  | DE/CA09/00091641           |
| ABT-DOA-B176           | Accu-Tell® KET Cassette                      | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC    | "Other"         | N/A                                  | DE/CA09/00091641           |

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|------------------------|------------------------------------------------------|-----------------------------------|--------------------|----------------------------------------------------------------|-----------------|--------------------------------------|----------------------------|
| ABT-DOA-B171           | Accu-Tell® OXY Cassette                              | Cassette                          | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC                       | "Other"         | N/A                                  | DE/CA09/00091641           |
| ABT-ACH-A187           | Accu-Tell® Alcohol Strip                             | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC                       | "Other"         | N/A                                  | DE/CA09/00091641           |
| ABT-ACH-A188           | Accu-Tell® Alcohol Strip (Urine)                     | Strip                             | 12 70 09 90        | Other Drugs of Abuse/Toxicology RT & POC                       | "Other"         | N/A                                  | DE/CA09/00091641           |
| ABT-CT-A251            | Accu-Tell® CRP Test Semi-Quantitative Test           | Strip                             | 12 70 11 01        | C-Reactive Protein - RT & POC                                  | Other           | N/A                                  | DE/CA09/00091637           |
| ABT-CT-B251            | Accu-Tell® CRP Test Semi-Quantitative Test           | Cassette                          | 12 70 11 01        | C-Reactive Protein - RT & POC                                  | Other           | N/A                                  | DE/CA09/00091637           |
| ABT-INF-B318           | Accu-Tell® CRP Semi-Quantitative Cassette            | Cassette                          | 12 70 11 01        | C-Reactive Protein - RT & POC                                  | Other           | N/A                                  | DE/CA09/00091637           |
| ABT-CT-A66             | Accu-Tell® CK-MB Test                                | Strip                             | 12 70 13 01        | Creatine Kinase - MB mass - RT & POC                           | "Other"         | N/A                                  | DE/CA09/00090993           |
| ABT-CT-B66             | Accu-Tell® CK-MB Test                                | Cassette                          | 12 70 13 01        | Creatine Kinase - MB mass - RT & POC                           | "Other"         | N/A                                  | DE/CA09/00090993           |
| ABT-CT-A68             | Accu-Tell® Myoglobin Test                            | Strip                             | 12 70 13 02        | Myoglobin - RT & POC                                           | Other           | N/A                                  | DE/CA09/00091634           |
| ABT-CT-B68             | Accu-Tell® Myoglobin Test                            | Cassette                          | 12 70 13 02        | Myoglobin - RT & POC                                           | Other           | N/A                                  | DE/CA09/00091634           |
| ABT-CT-A111            | Accu-Tell® NT-proBNP Test                            | Strip                             | 12 70 13 04        | BNP / proBNP - RT & POC (Including other Natriuretic Peptides) | Other           | N/A                                  | DE/CA09/00091636           |
| ABT-CT-B111            | Accu-Tell® NT-proBNP Test                            | Cassette                          | 12 70 13 04        | BNP / proBNP - RT & POC (Including other Natriuretic Peptides) | Other           | N/A                                  | DE/CA09/00091636           |
| ABT-CT-E71             | Accu-Tell® Myoglobin/CK-MB/Troponin I Test           | Cassette                          | 12 70 13 70        | Multiple Cardiac Markers - RT & POC                            | Other           | N/A                                  | DE/CA09/00091635           |
| ABT-IDT-A266           | Accu-Tell® PCT Semi-Quantitative Test                | Strip                             | 12 70 90 90        | Other other RT and POC - Immunochemistry                       | "Other"         | N/A                                  | DE/CA09/00090960           |
| ABT-IDT-B266           | Accu-Tell® PCT Semi-Quantitative Test                | Cassette                          | 12 70 90 90        | Other other RT and POC - Immunochemistry                       | "Other"         | N/A                                  | DE/CA09/00090960           |
| ABT-CT-A110            | Accu-Tell® Rapid D-Dimer Test                        | Strip                             | 13 02 70 03        | D-Dimer - RT & POC                                             | "Other"         | N/A                                  | DE/CA09/00090992           |
| ABT-CT-B110            | Accu-Tell® Rapid D-Dimer Test                        | Cassette                          | 13 02 70 03        | D-Dimer - RT & POC                                             | "Other"         | N/A                                  | DE/CA09/00090992           |
| ABT-IDT-B370           | Accu-Tell® SARS-CoV-2+Flu A&B Antigen Combo Cassette | Cassette                          | 15 30 02 90        | Other Multiple Viruses - Multiplex Assays                      | "Other"         | N/A                                  | DE/CA09/00098842           |
| ABT-IDT-A13            | Accu-Tell® H. pylori IgG Strip                       | Strip                             | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-B13            | Accu-Tell® H. pylori IgG Cassette                    | Cassette                          | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-B76            | Accu-Tell® Rapid H. pylori Antigen Test              | Cassette                          | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-B262           | Accu-Tell® H. pylori IgG Cassette                    | Cassette                          | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-B385           | Accu-Tell® H. pylori IgG/IgM/IgA Cassette            | Cassette                          | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-A385           | Accu-Tell® H. pylori IgG/IgM/IgA Strip               | Strip                             | 15 70 01 02        | H. Pylori - RT & POC                                           | "Other"         | N/A                                  | DE/CA09/00087396           |
| ABT-IDT-B15            | Accu-Tell® Rapid Strep A Test                        | Cassette                          | 15 70 01 03        | Strep A - RT & POC                                             | "Other"         | N/A                                  | DE/CA09/00087264           |
| ABT-IDT-A15            | Accu-Tell® Rapid Strep A Test                        | Strip                             | 15 70 01 03        | Strep A - RT & POC                                             | "Other"         | N/A                                  | DE/CA09/00087264           |

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| 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-STD-A60            | Accu-Tell® Rapid Syphilis Test                                    | Strip                             | 15 70 01 05        | Syphilis - RT & POC                                    | "Other"         | N/A                                  | DE/CA09/00088771           |
| ABT-STD-B60            | Accu-Tell® Rapid Syphilis Test                                    | Cassette                          | 15 70 01 05        | Syphilis - RT & POC                                    | "Other"         | N/A                                  | DE/CA09/00088771           |
| ABT-STD-A17            | Accu-Tell® Syphilis Strip                                         | Strip                             | 15 70 01 05        | Syphilis - RT & POC                                    | "Other"         | N/A                                  | DE/CA09/00088771           |
| ABT-STD-B17            | Accu-Tell® Syphilis Cassette                                      | Cassette                          | 15 70 01 05        | Syphilis - RT & POC                                    | "Other"         | N/A                                  | DE/CA09/00088771           |
| ABT-IDT-8315           | Accu-Tell® Clostridium difficile GDH Test                         | Cassette                          | 15 70 01 06        | Clostr. diff. incl GDH and/or Toxin A and B - RT & POC | "Other"         | N/A                                  | DE/CA09/00090962           |
| ABT-IDT-8316           | Accu-Tell® Clostridium difficile GDH +Toxin A+ Toxin B Combo Test | Cassette                          | 15 70 01 06        | Clostr. diff. incl GDH and/or Toxin A and B - RT & POC | "Other"         | N/A                                  | DE/CA09/00090962           |
| ABT-IDT-8314           | Accu-Tell® Clostridium difficile Toxin A+ Toxin B Combo Test      | Cassette                          | 15 70 01 06        | Clostr. diff. incl GDH and/or Toxin A and B - RT & POC | "Other"         | N/A                                  | DE/CA09/00090962           |
| ABT-IDT-8303           | Accu-Tell® Legionella Test                                        | Cassette                          | 15 70 01 08        | Legionella - RT & POC                                  | "Other"         | N/A                                  | DE/CA09/00093544           |
| ABT-IDT-A57            | Accu-Tell® Rapid Tuberculosis Test                                | Strip                             | 15 70 01 90        | Other Bacteriology - RT & POC                          | "Other"         | N/A                                  | DE/CA09/00087397           |
| ABT-IDT-857            | Accu-Tell® Rapid Tuberculosis Test                                | Cassette                          | 15 70 01 90        | Other Bacteriology - RT & POC                          | "Other"         | N/A                                  | DE/CA09/00087397           |
| -                      | Accu-Tell® Rapid Typhoid Test                                     | Cassette                          | 15 70 01 90        | Other Bacteriology - RT & POC                          | "Other"         | N/A                                  | DE/CA09/00087397           |
| ABT-IDT-8260           | Accu-Tell® TB Cassette                                            | Cassette                          | 15 70 01 90        | Other Bacteriology - RT & POC                          | "Other"         | N/A                                  | DE/CA09/00087397           |
| ABT-IDT-8263           | Accu-Tell® Typhoid Cassette                                       | Cassette                          | 15 70 01 90        | Other Bacteriology - RT & POC                          | "Other"         | N/A                                  | DE/CA09/00087397           |
| ABT-IDT-A218           | Accu-Tell® HAV IgM Test                                           | Strip                             | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-B218           | Accu-Tell® HAV IgM Test                                           | Cassette                          | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-A226           | Accu-Tell® HAV IgM/IgG Test                                       | Strip                             | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-B226           | Accu-Tell® HAV IgM/IgG Cassette                                   | Cassette                          | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-B246           | Accu-Tell® HEV IgM Cassette                                       | Cassette                          | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-B231           | Accu-Tell® HAV IgG Cassette                                       | Cassette                          | 15 70 02 90        | Other Hepatitis Viruses - RT & POC                     | Other           | N/A                                  | DE/CA09/00092337           |
| ABT-IDT-858            | Accu-Tell® Rapid Malaria P.f. /P.v. Test                          | Cassette                          | 15 70 05 01        | Plasmodium (Malaria) - RT & POC                        | "Other"         | N/A                                  | DE/CA09/00089311           |
| ABT-IDT-B236           | Accu-Tell® Rapid Malaria P.f. /P.v./Pan Test                      | Cassette                          | 15 70 05 01        | Plasmodium (Malaria) - RT & POC                        | "Other"         | N/A                                  | DE/CA09/00089311           |
| ABT-IDT-A99            | Accu-Tell® Rapid Malaria P.f. /Pan Test                           | Strip                             | 15 70 05 01        | Plasmodium (Malaria) - RT & POC                        | "Other"         | N/A                                  | DE/CA09/00089311           |
| ABT-IDT-B99            | Accu-Tell® Rapid Malaria P.f. /Pan Test                           | Cassette                          | 15 70 05 01        | Plasmodium (Malaria) - RT & POC                        | "Other"         | N/A                                  | DE/CA09/00089311           |
| ABT-IDT-885            | Accu-Tell® Malaria P.f. Cassette                                  | Cassette                          | 15 70 05 01        | Plasmodium (Malaria) - RT & POC                        | "Other"         | N/A                                  | DE/CA09/00089311           |
| ABT-IDT-A219           | Accu-Tell® Chagas Test                                            | Strip                             | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-B219           | Accu-Tell® Chagas Test                                            | Cassette                          | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-A292           | Accu-Tell® Entamoeba histolytica Test                             | Strip                             | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-B292           | Accu-Tell® Entamoeba histolytica Test                             | Cassette                          | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-A255           | Accu-Tell® Giardia lamblia Test                                   | Strip                             | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-B255           | Accu-Tell® Giardia lamblia Test                                   | Cassette                          | 15 70 05 90        | Other Parasites - RT & POC                             | Other           | N/A                                  | DE/CA09/00091861           |
| ABT-IDT-B296           | Accu-Tell® RSV Antigen Cassette                                   | Cassette                          | 15 70 90 02        | RSV - RT & POC                                         | Other           | N/A                                  | DE/CA09/00103063           |

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|------------------------|------------------------------------------------------|------------------------|--------------------|----------------------------------|-----------------|--------------------------------------|----------------------------|
| ABT-IDT-A247           | Accu-Tell® Influenza A+B Test                        | Strip                  | 15 70 90 04        | Influenza A and /or B - RT & POC | Other           | N/A                                  | DE/CA09/00092338           |
| ABT-IDT-B247           | Accu-Tell® Influenza A+B Test                        | Cassette               | 15 70 90 04        | Influenza A and /or B - RT & POC | Other           | N/A                                  | DE/CA09/00092338           |
| ABT-IDT-B97            | Accu-Tell® Rapid Dengue IgG/IgM Test                 | Cassette               | 15 70 90 07        | Dengue - RT & POC                | "Other"         | N/A                                  | DE/CA09/00087425           |
| ABT-IDT-B217           | Accu-Tell® Rapid Dengue IgG/IgM/NS1 Test             | Cassette               | 15 70 90 07        | Dengue - RT & POC                | "Other"         | N/A                                  | DE/CA09/00087425           |
| ABT-IDT-B216           | Accu-Tell® Rapid Dengue NS1 Test                     | Cassette               | 15 70 90 07        | Dengue - RT & POC                | "Other"         | N/A                                  | DE/CA09/00087425           |
| ABT-IDT-B274           | Accu-Tell® Dengue NS1 Antigen Cassette               | Cassette               | 15 70 90 07        | Dengue - RT & POC                | "Other"         | N/A                                  | DE/CA09/00087425           |
| ABT-IDT-B259           | Accu-Tell® Dengue IgG/IgM/NS1 Combo Cassette         | Cassette               | 15 70 90 07        | Dengue - RT & POC                | "Other"         | N/A                                  | DE/CA09/00087425           |
| ABT-IDT-B371;          | Accu-Tell® SARS-CoV-2 Neutralizing Antibody Cassette | Cassette               | 15 70 90 08        | Coronavirus - RT & POC           | "Other"         | N/A                                  | DE/CA09/00098928           |
| ABT-IDT-B373           | Cassette                                             |                        |                    |                                  |                 |                                      |                            |
| ABT-IDT-B372;          | Accu-Tell® COVID-19 Antigen Cassette                 | Cassette               | 15 70 90 08        | Coronavirus - RT & POC           | "Other"         | N/A                                  | DE/CA09/00098928           |
| ABT-IDT-B374;          |                                                      |                        |                    |                                  |                 |                                      |                            |
| ABT-IDT-B384;          |                                                      |                        |                    |                                  |                 |                                      |                            |
| ABT-IDT-B378           |                                                      |                        |                    |                                  |                 |                                      |                            |
| ABT-IDT-B352           | Accu-Tell® COVID-19 IgG/IgM Cassette                 | Cassette               | 15 70 90 08        | Coronavirus - RT & POC           | "Other"         | N/A                                  | DE/CA09/00098928           |
| ABT-IDT-B367           | Accu-Tell® SARS-CoV-2 Ag Cassette                    | Cassette               | 15 70 90 08        | Coronavirus - RT & POC           | "Other"         | N/A                                  | DE/CA09/00098928           |
| ABT-IDT-B256           | Accu-Tell® Norovirus Test                            | Cassette               | 15 70 90 90        | Other Other Virology RT & POC    | "Other"         | N/A                                  | DE/CA09/00087394           |
| -                      | Accu-Tell® Rapid Chikungunya IgG/IgM Test            | Cassette               | 15 70 90 90        | Other Other Virology RT & POC    | "Other"         | N/A                                  | DE/CA09/00087394           |
| ABT-IDT-B63            | Accu-Tell® Rotavirus Test                            | Cassette               | 15 70 90 90        | Other Other Virology RT & POC    | "Other"         | N/A                                  | DE/CA09/00087394           |
| ABT-IDT-B64            | Accu-Tell® Rotavirus/Adenovirus Test                 | Cassette               | 15 70 90 90        | Other Other Virology RT & POC    | "Other"         | N/A                                  | DE/CA09/00087394           |