



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:

CTK Biotech, Inc.
13855 Stowe Dr.
Poway, CA 92064
USA

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 2022-06-30

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.

2022-06-30

Dr. Philipp Hohenbrink
Director AR Services
MDSS GmbH

Annex A: 2022-06-30
Manufacturer: CTK Biotech, Inc.

REF	Device Names (notified)	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
F2021	RaFIA Cys-C FIA Test	EDMA	12 01 90 09	Cystatin C	Other	N/A	DE/CA09/00097959
F2015	RaFIA CEA FIA Test	EDMA	12 03 01 31	Carcinoembryonic Antigen	Other	N/A	DE/CA09/00097960
F2030	RaFIA AFP FIA Test	EDMA	12 03 90 01	Alphafetoprotein	Other	N/A	DE/CA09/00097961
E1011	RecombiLISA Free T3 ELISA; Aria Free T3 ELISA	EDMA	12 04 01 01	Free Triiodothyronine	Other	N/A	DE/CA09/00089594
E1016	CTK fT3 ELISA	EDMA	12 04 01 01	Free Triiodothyronine	Other	N/A	DE/CA09/00089594
L1016	RapidLight free T3 CLIA Test	EDMA	12 04 01 01	Free Triiodothyronine	Other	N/A	DE/CA09/00089594
E1021	RecombiLISA Free T4 ELISA; Aria Free T4 ELISA	EDMA	12 04 01 02	Free Thyroxine	Other	N/A	DE/CA09/00089595
E1026	CTK fT4 ELISA	EDMA	12 04 01 02	Free Thyroxine	Other	N/A	DE/CA09/00089595
L1026	RapidLight free T4 CLIA Test	EDMA	12 04 01 02	Free Thyroxine	Other	N/A	DE/CA09/00089595
E1010	RecombiLISA Total T3 ELISA; Aria Total T3 ELISA	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/00080012
E1015	CTK Total Triiodothyronine (T3) ELISA	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/00080012
F1015	RaFIA T3 FIA Test	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/00080012
L1015	RapidLight Total T3 CLIA Test	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/00080012
E1020	RecombiLISA Total T4 ELISA; Aria Total T4 ELISA	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/00080013
E1025	CTK Total Thyroxine (T4) ELISA	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/00080013
F1025	RaFIA T4 FIA Test	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/00080013
L1025	RapidLight Total T4 CLIA Test	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/00080013
E1035	CTK TSH ELISA	EDMA	12 04 01 11	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/00080014
F1030	RaFIA TSH FIA Test	EDMA	12 04 01 11	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/00080014
E1030	RecombiLISA TSH ELISA; Aria TSH ELISA	EDMA	12 04 01 11	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/00080014
L1030	RapidLight TSH CLIA Test	EDMA	12 04 01 11	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/00080014



Annex A: 2022-06-30
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E1230	CTK Estradiol (E2) ELISA	EDMA	12 05 01 03	Estradiol	Other	N/A	DE/CA09/00090864
L1230	RapidLight E2 CLIA Test	EDMA	12 05 01 03	Estradiol	Other	N/A	DE/CA09/00090864
E1100	CTK FSH ELISA	EDMA	12 05 01 04	Follicle Stimulating Hormone	Other	N/A	DE/CA09/00090865
F1100	RaFIA FSH FIA Test	EDMA	12 05 01 04	Follicle Stimulating Hormone	Other	N/A	DE/CA09/00090865
L1100	RapidLight FSH CLIA Test	EDMA	12 05 01 04	Follicle Stimulating Hormone	Other	N/A	DE/CA09/00090865
E1090	CTK LH ELISA	EDMA	12 05 01 05	Luteinising Hormone	Other	N/A	DE/CA09/00090866
F1090	RaFIA LH FIA Test	EDMA	12 05 01 05	Luteinising Hormone	Other	N/A	DE/CA09/00090866
L1090	RapidLight LH CLIA Test	EDMA	12 05 01 05	Luteinising Hormone	Other	N/A	DE/CA09/00090866
E1220	CTK Progesterone ELISA	EDMA	12 05 01 06	Progesterone	Other	N/A	DE/CA09/00090867
F1220	RaFIA Progesterone FIA Test	EDMA	12 05 01 06	Progesterone	Other	N/A	DE/CA09/00090867
L1220	RapidLight Progesterone CLIA Test	EDMA	12 05 01 06	Progesterone	Other	N/A	DE/CA09/00090867
E1080	CTK PRL ELISA	EDMA	12 05 01 08	Prolactin	Other	N/A	DE/CA09/00090868
F1080	RaFIA PRL FIA Test	EDMA	12 05 01 08	Prolactin	Other	N/A	DE/CA09/00090868
L1080	RapidLight PRL CLIA Test	EDMA	12 05 01 08	Prolactin	Other	N/A	DE/CA09/00090868
E1210	CTK Testosterone ELISA	EDMA	12 05 01 10	Testosterone (with Dehydro and Free Testosterone)	Other	N/A	DE/CA09/00090869
F1210	RaFIA Testosterone FIA Test	EDMA	12 05 01 10	Testosterone (with Dehydro and Free Testosterone)	Other	N/A	DE/CA09/00090869
L1210	RapidLight Testosterone CLIA Test	EDMA	12 05 01 10	Testosterone (with Dehydro and Free Testosterone)	Other	N/A	DE/CA09/00090869
E1000	CTK hCG ELISA	EDMA	12 05 02 05	Human Chorionic Gonadotropin Total	Other	N/A	DE/CA09/00090870
F1000	RaFIA β -hCG FIA Test	EDMA	12 05 02 06	β -Human Chorionic Gonadotropin (incl. subunit)	Other	N/A	DE/CA09/00095411

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L1000	RapidLight β -hCG CLIA Test	EDMA	12 05 02 06	β -Human Chorionic Gonadotropin (incl. subunit)	Other	N/A	DE/CA09/00095411
E1240	CTK AMH ELISA	EDMA	12 05 02 16	Anti-Müllerian Hormone	Other	N/A	DE/CA09/00097852
F1240	RaFIA AMH FIA Test	EDMA	12 05 02 16	Anti-Müllerian Hormone	Other	N/A	DE/CA09/00097852
L1240	RapidLight AMH CLIA Test	EDMA	12 05 02 16	Anti-Müllerian Hormone	Other	N/A	DE/CA09/00097852
F0400	RaFIA PCT FIA Test	EDMA	12 06 90 16	Procalcitonin	Other	N/A	DE/CA09/00095412
L0400	RapidLight PCT CLIA Test	EDMA	12 06 90 16	Procalcitonin	Other	N/A	DE/CA09/00095412
F5010	RaFIA Ferritin FIA Test	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/00096567
L5010	RapidLight Ferritin CLIA Test	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/00096567
E5010	CTK Ferritin ELISA	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/00096567
L8020	RapidLight Folate CLIA Test	EDMA	12 07 01 03	Folate	Other	N/A	DE/CA09/00104460
E8030	CTK Vitamin B12 ELISA	EDMA	12 07 02 04	Vitamin B12	Other	N/A	DE/CA09/00090871
L8030	RapidLight Vitamin B12 CLIA Test	EDMA	12 07 02 04	Vitamin B12	Other	N/A	DE/CA09/00090871
E8010	CTK Vitamin D (Total) ELISA	EDMA	12 07 02 05	Vitamin D (Cholecalciferol)	Other	N/A	DE/CA09/00090872
L8010	RapidLight Total Vitamin D CLIA Test	EDMA	12 07 02 05	Vitamin D (Cholecalciferol)	Other	N/A	DE/CA09/00090872
F8010	RaFIA Total Vitamin D FIA Test	EDMA	12 07 02 05	Vitamin D (Cholecalciferol)	Other	N/A	DE/CA09/00090872
L3050	RapidLight NT-proBNP CLIA Test	EDMA	12 13 01 01	BNP / proBNP (including other Natriuretic Peptides)	Other	N/A	DE/CA09/00099508
F3020	RaFIA CK-MB FIA Test	EDMA	12 13 01 02	Creatine Kinase - MB "Mass"	Other	N/A	DE/CA09/00096565
L3020	RapidLight CK-MB CLIA Test	EDMA	12 13 01 02	Creatine Kinase - MB "Mass"	Other	N/A	DE/CA09/00096565
F3030	RaFIA MYO FIA Test	EDMA	12 13 01 05	Myoglobin	Other	N/A	DE/CA09/00096566
L3030	RapidLight Myoglobin CLIA Test	EDMA	12 13 01 05	Myoglobin	Other	N/A	DE/CA09/00096566
L3002	RapidLight cTnI CLIA Test	EDMA	12 13 01 07	Troponin I/T	Other	N/A	DE/CA09/00099509
L3003	RapidLight hs-cTnI CLIA Test	EDMA	12 13 01 07	Troponin I/T	Other	N/A	DE/CA09/00099509

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F2020	RaFIA MAU FIA Test	EDMA	12 70 01 01	Albumin incl. uAlbumin RT & POC	Other	N/A	DE/CA09/00095413
F6100	RaFIA HbA1c FIA Test	EDMA	12 70 01 02	Glycosylated/Glycated Haemoglobin (IC) - RT & POC	Other	N/A	DE/CA09/00095414
R2010C	OnSite FOB Rapid Test; Aria FOB Rapid Test	EDMA	12 70 03 90	Other Tumour Marker RT & POC	Other	N/A	DE/CA09/00080015
R2011C	OnSite FOB-Hi Rapid Test; ad-bio FOB-Hi Rapid Test; Aria FOB-Hi Rapid Test	EDMA	12 70 03 90	Other Tumour Marker RT & POC	Other	N/A	DE/CA09/00080015
R1000C	OnSite hCG Urine Rapid Test; Aria hCG Urine Rapid Test	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/00080017
R1000S	OnSite hCG Urine Rapid Test; ad-bio hCG Urine Rapid Test; Aria hCG Urine Rapid Test	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/00080017
R1001C	OnSite hCG Combo Rapid Test; ad-bio hCG Combo Rapid Test; Aria hCG Combo Rapid Test	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/00080017
R1001S	OnSite hCG Combo Rapid Test; ad-bio hCG Combo Rapid Test; Aria hCG Combo Rapid Test	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/00080017
F0410	RaFIA CRP FIA Test	EDMA	12 70 11 01	C-Reactive Protein - RT & POC	Other	N/A	DE/CA09/00095415
R0310C	OnSite RF Rapid Test; Aria RF Rapid Test	EDMA	12 70 11 90	Other Rheumatoid / Inflammatory Disease RT & POC	Other	N/A	DE/CA09/00084404
R3001C	OnSite Troponin I Rapid Test; ad-bio Troponin I Rapid Test; Aria Troponin I Rapid Test	EDMA	12 70 13 03	Troponin I/T - RT & POC	Other	N/A	DE/CA09/00080020
R3002C	OnSite Troponin I Combo Rapid Test; ad-bio Troponin I Combo Rapid Test; Aria Troponin I Combo Rapid Test	EDMA	12 70 13 03	Troponin I/T - RT & POC	Other	N/A	DE/CA09/00080020
F3002	RaFIA cTnI FIA Test	EDMA	12 70 13 03	Troponin I/T - RT & POC	Other	N/A	DE/CA09/00080020

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F3050	RaFIA NT-proBNP FIA Test	EDMA	12 70 13 04	BNP / proBNP - RT & POC (including other Natriuretic Peptides)	Other	N/A	DE/CA09/00095417
C0187	Positivita Influenza A/B Rapid Test External Control Kit	EDMA	12 70 50 50	Controls Immunochem - RT & POC	Other	N/A	DE/CA09/00087727
C2011	Positivita FOB Rapid Test External Control Kit	EDMA	12 70 50 50	Controls Immunochem - RT & POC	Other	N/A	DE/CA09/00087727
F3010	RaFIA D-Dimer FIA Test	EDMA	13 02 05 03	D-Dimer	Other	N/A	DE/CA09/00096564
L3010	RapidLight D-Dimer CLIA Test	EDMA	13 02 05 03	D-Dimer	Other	N/A	DE/CA09/00096564
P0180	Aridia COVID-19 Real-Time PCR Test	EDMA	15 04 40 19	Coronavirus - NA Reagents	Other	N/A	DE/CA09/00095418
E0610	RecombiLISA Syphilis Ab ELISA; Aria Syphilis Ab ELISA	EDMA	15 01 03 03	Syphilis Antibody Assays Total	Other	N/A	DE/CA09/00080021
P0030H P0030L	Aridia T. Pallidum Real-Time PCR Test	EDMA	15 01 03 40	Syphilis detection by NA Reagents	Other	N/A	DE/CA09/00093455
C0192	Positivita H. pylori Ag Rapid Test External Control Kit	EDMA	15 01 04 90	Other H. pylori Reagents	Other	N/A	DE/CA09/00090873
E0330	RecombiLISA Lepto IgM ELISA; Aria Lepto IgM ELISA	EDMA	15 01 90 04	Leptospira	Other	N/A	DE/CA09/00080023
E0100	RecombiLISA HAV IgM ELISA; Aria HAV IgM ELISA	EDMA	15 02 01 06	HAV Antibody IgM	Other	N/A	DE/CA09/00080025
E0105	RecombiLISA HEV IgM ELISA; Aria HEV IgM ELISA	EDMA	15 02 05 06	HEV Antibody IgM	Other	N/A	DE/CA09/00080026
R0203C	OnSite HSV-1 IgG/IgM Rapid Test; Aria HSV-1 IgG/IgM Rapid Test	EDMA	15 04 03 07	HSV 1 Antibodies - Total	Other	N/A	DE/CA09/00085817
R0213C	OnSite HSV-2 IgG/IgM Rapid Test; Aria HSV-2 IgG/IgM Rapid Test	EDMA	15 04 03 10	HSV 2 Antibodies - Total	Other	N/A	DE/CA09/00085818
R0218C	OnSite Duo HSV-1/2 IgG/IgM Rapid Test; Aria Duo HSV-1/2 IgG/IgM Rapid Test	EDMA	15 04 03 90	Other HSV Reagents	Other	N/A	DE/CA09/00090874
F0182	RaFIA COVID-19 Ag FIA Test	EDMA	15 04 09 01	Coronavirus Ag	Other	N/A	DE/CA09/00100687
P0188H P0188L	Aridia Influenza A Typing Real-Time PCR Test	EDMA	15 04 40 04	Influenza & Para Influenza - NA Reagents	Other	N/A	DE/CA09/00094271

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P0060H P0060L	Aridia Dengue Virus Real-Time PCR Test	EDMA	15 04 40 11	Dengue Virus - NA Reagents	Other	N/A	DE/CA09/00089274
P0061H P0061L	Aridia Dengue Serotyping Real-Time PCR Test	EDMA	15 04 40 11	Dengue Virus - NA Reagents	Other	N/A	DE/CA09/00089274
P0066H P0066L	Aridia Chikungunya Virus Real-Time PCR Test	EDMA	15 04 40 25	Chikungunya Virus - NA Reagents	Other	N/A	DE/CA09/00089275
P0148H P0148L	Aridia West Nile Virus Real-Time PCR Test	EDMA	15 04 40 26	West Nile Virus - NA Reagent	Other	N/A	DE/CA09/00092894
P0070H P0070L	Aridia Zika Virus Real-Time PCR Test	EDMA	15 04 40 30	Zika Virus - NA Reagents	Other	N/A	DE/CA09/00099660
P0036H P0036L	Aridia HPV 16/18 Real-Time PCR Test	EDMA	15 04 40 41	Human Papilloma Virus Genotyping - NA Reagents	Other	N/A	DE/CA09/00093456
R0189C	OnSite Adenovirus Ag Rapid Test; Aria Adenovirus Ag Rapid Test	EDMA	15 04 80 01	Adenovirus	Other	N/A	DE/CA09/00093457
E0310	RecombiLISA Dengue IgM ELISA; Aria Dengue IgM ELISA	EDMA	15 04 80 11	Dengue Virus	Other	N/A	DE/CA09/00080031
E0311	RecombiLISA Dengue IgG ELISA; Aria Dengue IgG ELISA	EDMA	15 04 80 11	Dengue Virus	Other	N/A	DE/CA09/00080031
E0312	RecombiLISA Dengue Ag ELISA; Aria Dengue Ag ELISA	EDMA	15 04 80 11	Dengue Virus	Other	N/A	DE/CA09/00080031
E0315	RecombiLISA CHIK IgM ELISA; Aria CHIK IgM ELISA	EDMA	15 04 80 25	Chikungunya Virus	Other	N/A	DE/CA09/00080032
R0068C E0320	OnSite Chikungunya IgG/IgM Combo Rapid Test RecombiLISA Zika IgM ELISA; Aria Zika IgM ELISA	EDMA	15 04 80 30	Zika Virus	Other	N/A	DE/CA09/00089228
R0188C	OnSite COVID-19 + Influenza A/B Ag Rapid Test; Aria COVID-19 + Influenza A/B Ag Rapid Test	EDMA	15 04 80 90	Other Viral Antigen/Antibody Detection	Other	N/A	DE/CA09/00098579
F0188	RaFIA COVID-19 + Influenza A/B Ag FIA Test	EDMA	15 04 80 90	Other Viral Antigen/Antibody Detection	Other	N/A	DE/CA09/00098579

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E0170	RecombiLISA Chagas IgG ELISA; Aria Chagas IgG ELISA	EDMA	15 05 10 02	Chagas	Other	N/A	DE/CA09/00080034
E0121	RecombiLISA Leishmania Ab ELISA; Aria Leishmania Ab ELISA	EDMA	15 05 10 05	Leishmania	Other	N/A	DE/CA09/00080035
P0189	Aridia SARS-CoV-2 & Influenza A/B Real-Time PCR Test	EDMA	15 30 02 42	Influenza & Para Influenza / Respiratory Syncytial Virus (RSV) / SARS-CoV - Multiplex NA Reagents	Other	N/A	DE/CA09/00099659
P0186	Aridia SARS-CoV-2, Influenza A/B & RSV A/B Real- Time PCR Test	EDMA	15 30 02 42	Influenza & Para Influenza / Respiratory Syncytial Virus (RSV) / SARS-CoV - Multiplex NA Reagents	Other	N/A	DE/CA09/00099659
P0071H P0071L	Aridia Zika/Dengue/CHIK Real-Time PCR Test	EDMA	15 30 02 90	Other Multiple Infectious - Multiplex Assays	Other	N/A	DE/CA09/00089276
P0182H P0182L	Aridia Rhinovirus/Enterovirus Real-Time PCR Test	EDMA	15 30 02 90	Other Multiple Infectious - Multiplex Assays	Other	N/A	DE/CA09/00089276
P0187H P0187L	Aridia Influenza A/B & RSV Real-Time PCR Test	EDMA	15 30 02 90	Other Multiple Infectious - Multiplex Assays	Other	N/A	DE/CA09/00089276
P0218H P0218L	Aridia HSV1/HSV2/T. pallidum Real-Time PCR Test	EDMA	15 30 02 90	Other Multiple Infectious - Multiplex Assays	Other	N/A	DE/CA09/00089276
C0180	Positivia COVID-19 IgG/IgM Rapid Test External Control Kit	EDMA	15 50 01 04	Other Virology Controls - Inf.imm.	Other	N/A	DE/CA09/00098580
C0063	Positivia Dengue Ag Rapid Test External Control Kit	EDMA	15 50 01 04	Other Virology Controls - Inf.imm.	Other	N/A	DE/CA09/00098580

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C0182	Positivia COVID-19 Ag Rapid Test External Control Kit	EDMA	15 50 01 04	Other Virology Controls - Inf. Imm.	Other	N/A	DE/CA09/00098580
C0065	Positivia Dengue IgG Rapid Test External Control Kit	EDMA	15 50 01 04	Other Virology Controls - Inf. Imm.	Other	N/A	DE/CA09/00098580
R0190C	OnSite H. pylori Ab Rapid Test; Aria H. pylori Ab Rapid Test	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	DE/CA09/00080036
R0191C	OnSite H. pylori Ab combo Rapid Test; ad-bio H. pylori Ab combo Rapid Test;	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	DE/CA09/00080036
R0192C	Aria H. pylori Ab combo Rapid Test OnSite H. pylori Ag Rapid Test; ad-bio H. pylori Ag Rapid Test;	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	DE/CA09/00080036
R0192S	Aria H. pylori Ag Rapid Test; OnSite H. pylori Ag Rapid Test; Aria H. pylori Ag Rapid Test	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	DE/CA09/00080036
R0184C	OnSite Strep A Rapid Test; Aria Strep A Rapid Test	EDMA	15 70 01 03	Strep. A - RT & POC	Other	N/A	DE/CA09/00080037
R0184S	OnSite Strep A Rapid Test; ad-bio Strep A Rapid Test; Aria Strep A Rapid Test	EDMA	15 70 01 03	Strep. A - RT & POC	Other	N/A	DE/CA09/00080037
R0030C	OnSite Syphilis Ab Rapid Test; ad-bio Syphilis Ab Rapid Test;	EDMA	15 70 01 05	Syphilis - RT & POC	Other	N/A	DE/CA09/00080038
R0030S	Aria Syphilis Ab Rapid Test OnSite Syphilis Ab Rapid Test; Aria Syphilis Ab Rapid Test	EDMA	15 70 01 05	Syphilis - RT & POC	Other	N/A	DE/CA09/00080038
R0031C	OnSite Syphilis Ab Combo Rapid Test; ad-bio Syphilis Ab Combo Rapid Test; Aria Syphilis Ab Combo Rapid Test	EDMA	15 70 01 05	Syphilis - RT & POC	Other	N/A	DE/CA09/00080038
R0051C	OnSite TB IgG / IgM Rapid Test; ad-bio TB IgG / IgM Rapid Test; Aria TB IgG / IgM Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040

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R0053C	OnSite TB IgG / IgM Combo Rapid Test; ad-bio TB IgG / IgM Combo Rapid Test; Aria TB IgG / IgM Combo Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0085S	OnSite Gonorrhea Rapid Test; Aria Gonorrhea Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0130C	OnSite Cholera Ag Rapid Test; Aria Cholera Ag Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0160C	OnSite Typhoid IgG/IgM Rapid Test; Aria Typhoid IgG/IgM Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0161C	OnSite Typhoid IgG/IgM Combo Rapid Test; Aria Typhoid IgG/IgM Combo Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0163C	OnSite Typhoid Ag Rapid Test; Aria Typhoid Ag Rapid Test	EDMA	15 70 01 90	Other Bacteriology - RT & POC	Other	N/A	DE/CA09/00080040
R0042C	OnSite HBsAg Combo Rapid Test	EDMA	15 70 02 01	HBsAg - RT & POC	Annex II List A	2265/2020-IVD/QS- 008 exp. 2024-05-26 2265/2020-IVD/DE- 009 exp. 2024-05-26 2265/2020-IVD/QS- 008	DE/CA09/00099510
R0024C	OnSite HCV Ab Plus Combo Rapid Test	EDMA	15 70 02 02	HCV Antibody -RT & POC	Annex II List A	exp. 2024-05-26 2265/2020-IVD/DE- 009 exp. 2024-05-26	DE/CA09/00099511
R0090C	OnSite HAV IgM Rapid Test; ad-bio HAV IgM Rapid Test; Aria HAV IgM Rapid Test	EDMA	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00080041
R0092C	OnSite HAV IgG/IgM Rapid Test; Aria HAV IgG/IgM Rapid Test	EDMA	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00080041

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REF	Device Names (notified)	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
R0095C	OnSite HEV IgM Rapid Test; Aria HEV IgM Rapid Test	EDMA	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00080041
R0011C	OnSite HIV 1/2 Ab Plus Combo Rapid Test	EDMA	15 70 03 02	HIV 1 / 2 - RT & POC	Annex II List A	2265/2020-IVD/QS- 008 (2024-05-26) 2265/2020-IVD/DE- 009 (2024-05-26)	DE/CA09/00099512
R0110C	OnSite Malaria Pf/Pv Ab Rapid Test; Aria Malaria Pf/Pv Ab Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - RT & POC	Other	N/A	DE/CA09/00080042
R0111C	OnSite Malaria Pf/Pv Ab Combo Rapid Test; Aria Malaria Pf/Pv Ab Combo Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - RT & POC	Other	N/A	DE/CA09/00080042
R0112C	OnSite Malaria Pf/Pv Ag Rapid Test; ad-bio Malaria Pf/Pv Ag Rapid Test; Aria Malaria Pf/Pv Ag Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - RT & POC	Other	N/A	DE/CA09/00080042
R0113C	OnSite Malaria Pf/Pan Ag Rapid Test; ad-bio Malaria Pf/Pan Ag Rapid Test; Aria Malaria Pf/Pan Ag Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - RT & POC	Other	N/A	DE/CA09/00080042
R0114C	OnSite Malaria Pf Ag Rapid Test; Aria Malaria Pf Ag Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - RT & POC	Other	N/A	DE/CA09/00080042
R0121C	OnSite Leishmania IgG/IgM Combo Rapid Test; ad-bio Leishmania IgG/IgM Combo Rapid Test;	EDMA	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00080043
R0122S	Aria Leishmania IgG/IgM Combo Rapid Test	EDMA	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00080043
R0151C	OnSite Filariasis Ab Rapid Test; Aria Filariasis Ab Rapid Test	EDMA	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00080043
R0171C	OnSite Chagas Ab Combo Rapid Test; ad-bio Chagas Ab Combo Rapid Test; Aria Chagas Ab Combo Rapid Test	EDMA	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00080043
R0186C	OnSite RSV Ag Rapid Test; Aria RSV Ag Rapid Test	EDMA	15 70 90 02	RSV - RT & POC	Other	N/A	DE/CA09/00093458
R0187C	OnSite Influenza A/B Ag Rapid Test; Aria Influenza A/B Ag Rapid Test	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00080045

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R0187S	OnSite Influenza A/B Rapid Test; ad-bio Influenza A/B Rapid Test; Aria Influenza A/B Rapid Test	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00080045
R0181S	OnSite Influenza A/B Rapid Test with Positivaria External Controls; Aria Influenza A/B Rapid Test with Positivaria External Controls	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00080045
F0187	RaFIA Influenza A/B Ag FIA Test	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00080045
R0061C	OnSite Dengue IgG/IgM Combo Rapid Test; ad-bio Dengue IgG/IgM Combo Rapid Test; Aria Dengue IgG/IgM Combo Rapid Test	EDMA	15 70 90 07	Dengue - RT & POC	Other	N/A	DE/CA09/00080046
R0062C	OnSite Duo Dengue Ag - IgG/IgM Rapid Test; ad-bio Duo Dengue Ag - IgG/IgM Rapid Test; Aria Duo Dengue Ag - IgG/IgM Rapid Test	EDMA	15 70 90 07	Dengue - RT & POC	Other	N/A	DE/CA09/00080046
R0063C	OnSite Dengue Ag Rapid Test; ad-bio Dengue Ag Rapid Test; Aria Dengue Ag Rapid Test	EDMA	15 70 90 07	Dengue - RT & POC	Other	N/A	DE/CA09/00080046
R0065C	OnSite Dengue IgG Rapid Test; Aria Dengue IgG Rapid Test	EDMA	15 70 90 07	Dengue - RT & POC	Other	N/A	DE/CA09/00080046
R0180C	OnSite COVID-19 IgG/IgM Rapid Test; Aria COVID-19 IgG/IgM Rapid Test; Answer COVID-19 IgG/IgM Rapid Test SURGITECH COVID-19 IgG/IgM Rapid Test ad-bio COVID-19 IgG/IgM Rapid Test	EDMA	15 70 90 08	Coronavirus - RT & POC	Other	N/A	DE/CA09/00095264
R0182C	OnSite COVID-19 Ag Rapid Test Aria COVID-19 Ag Rapid Test Answer COVID-19 Ag Rapid Test ad-bio COVID-19 Ag Rapid Test ImmuView COVID-19 Ag Rapid Test SURGITECH COVID-19 Ag Rapid Test	EDMA	15 70 90 08	Coronavirus- RT & POC	Other	N/A	DE/CA09/00095264

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R0066C	OnSite Chikungunya IgM Combo Rapid Test; ad-bio Chikungunya IgM Combo Rapid Test; Aria Chikungunya IgM Combo Rapid Test	EDMA	15 70 90 90	Other Other Virology - RT & POC	Other	N/A	DE/CA09/00080047
R0069C	OnSite Duo Dengue IgG/IgM-CHIK IgM Rapid Test; Aria Duo Dengue IgG/IgM-CHIK IgM Rapid Test	EDMA	15 70 90 90	Other Other Virology - RT & POC	Other	N/A	DE/CA09/00080047
R0194C	OnSite Rotavirus Ag Rapid Test; Aria Rotavirus Ag Rapid Test	EDMA	15 70 90 90	Other Other Virology - RT & POC	Other	N/A	DE/CA09/00080047
R0196C	OnSite Rota/Adeno Ag Rapid Test; Aria Rota/Adeno Ag Rapid Test	EDMA	15 70 90 90	Other Other Virology - RT & POC	Other	N/A	DE/CA09/00080047
R0182CST	OnSite COVID-19 Ag Self Test	GMDN	65454	SARS-CoV-2 antigen IVD, kit, immuno- chromatographic test (ICT), self-testing	Self-Testing	2265/2021-IVD/DE- 015 exp. 2024-05-26	DE/CA09/00102096