



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 2020-03-17

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.

2020-03-17

Ludger Möller
President
MDSS GmbH

Annex A: 2020-03-17
Manufacturer: CTK Biotech, Inc.

REF	Device Names (notified)	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
E1011	RecombiLISA Free T3 ELISA Test; Aria Free T3 ELISA Test	EDMA	12 04 01 01	Free Triiodothyronine	Other	N/A	DE/CA09/0170/C33/IVD/036-02
E1016	CTK fT3 ELISA	EDMA	12 04 01 01	Free Triiodothyronine	Other	N/A	DE/CA09/0170/C33/IVD/036-02
E1021	RecombiLISA Free T4 ELISA Test; Aria Free T4 ELISA Test	EDMA	12 04 01 02	Free Thyroxine	Other	N/A	DE/CA09/0170/C33/IVD/035-03
E1026	CTK fT4 ELISA	EDMA	12 04 01 02	Free Thyroxine	Other	N/A	DE/CA09/0170/C33/IVD/035-03
E1010	RecombiLISA Total T3 ELISA Kit; Aria Total T3 ELISA Kit	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/0170/C33/IVD/027-04
E1015	CTK Total Triiodothyronine (T3) ELISA	EDMA	12 04 01 05	Triiodothyronine	Other	N/A	DE/CA09/0170/C33/IVD/027-04
E1020	RecombiLISA Total T4 ELISA Kit; Aria Total T4 ELISA Kit	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/0170/C33/IVD/027-04
E1025	CTK Total Thyroxine (T4) ELISA	EDMA	12 04 01 07	Thyroxine	Other	N/A	DE/CA09/0170/C33/IVD/027-04
E1030	RecombiLISA TSH ELISA Kit; Aria TSH ELISA Kit	EDMA	12 04 01 11 00	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/0170/C33/IVD/028-04
E1035	CTK TSH ELISA	EDMA	12 04 01 11 00	Thyroid Stimulating Hormone	Other	N/A	DE/CA09/0170/C33/IVD/028-04
E1230	CTK Estradiol (E2) ELISA	EDMA	12 05 01 03	Estradiol	Other	N/A	DE/CA09/0170/C33/IVD/047-01
E1100	CTK FSH ELISA	EDMA	12 05 01 04	Follicle Stimulating Hormone	Other	N/A	DE/CA09/0170/C33/IVD/046-01
E1090	CTK LH ELISA	EDMA	12 05 01 05	Luteinising Hormone	Other	N/A	DE/CA09/0170/C33/IVD/045-01
E1220	CTK Progesterone ELISA	EDMA	12 05 01 06	Progesterone	Other	N/A	DE/CA09/0170/C33/IVD/044-01
E1080	CTK PRL ELISA	EDMA	12 05 01 08	Prolactin	Other	N/A	DE/CA09/0170/C33/IVD/043-01

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E1210	CTK Testosterone ELISA	EDMA	12 05 01 10	Testosterone (with Dehydro and Free Testosterone)	Other	N/A	DE/CA09/0170/C33/IVD/042-01
E1000	CTK hCG ELISA	EDMA	12 05 02 05	Human Chorionic Gonadotropin Total	Other	N/A	DE/CA09/0170/C33/IVD/041-01
E8030	CTK Vitamin B12 ELISA	EDMA	12 07 02 04	Vitamin B12	Other	N/A	DE/CA09/0170/C33/IVD/040-01
E8010	CTK Vitamin D (Total) ELISA	EDMA	12 07 02 05	Vitamin D (Cholecalciferol)	Other	N/A	DE/CA09/0170/C33/IVD/039-01
R2010C	Onsite FOB Rapid Test (50ng/ml); Aria FOB Rapid Test (50ng/ml) Rapid Test	EDMA	12 70 03 90 00	Other Tumour Marker Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/006-03
R2011C	Onsite FOB-Hi Rapid Test (25ng/ml); ad-bio FOB-Hi Rapid Test (25ng/ml) Rapid Test; Aria FOB-Hi Rapid Test (25ng/ml) Rapid Test	EDMA	12 70 03 90 00	Other Tumour Marker Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/006-03
R1000C	Onsite HCG Urine Rapid Test; Aria HCG Urine Rapid Test	EDMA	12 70 05 02 00	HCG - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/009-02
R1000S	Onsite HCG Urine Rapid Test; ad-bio HCG Urine Rapid Test; Aria HCG Urine Rapid Test	EDMA	12 70 05 02 00	HCG - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/009-02
R1001C	Onsite HCG Combo Rapid Test; ad-bio HCG Combo Rapid Test; Aria HCG Combo Rapid Test	EDMA	12 70 05 02 00	HCG - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/009-02
R1001S	Onsite HCG Combo Rapid Test; ad-bio HCG Combo Rapid Test; Aria HCG Combo Rapid Test	EDMA	12 70 05 02 00	HCG - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/009-02
R0310C	Onsite RF Rapid Test; Aria RF Rapid Test	EDMA	12 70 11 90	Other Rheumatoid / Inflammatory Disease RT & POC	Other	N/A	DE/CA09/0170/C33/IVD/003-01
R3001C	Onsite Troponin I Rapid Test; ad-bio Troponin I Rapid Test; Aria Troponin I Rapid Test	EDMA	12 70 13 03 00	Troponin I/T - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/017-02

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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 00	Troponin I/T - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/017-02
C0187	Positivita Influenza A/B Rapid Test External Control Kit	EDMA	12 70 50 50	Controls Immunochem - RT & POC	Other	N/A	DE/CA09/0170/C33/IVD/029-01
E0610	RecombiLISA Syphilis Ab Test; Aria Syphilis Ab Test	EDMA	15 01 03 03 00	Syphilis Antibody Assays Total	Other	N/A	DE/CA09/0170/C33/IVD/025-02
P0030H P0030L	Aridia T. Pallidum Real-Time PCR Test	EDMA	15 01 03 40	Syphilis detection by NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/049 '00149614
C0192	Positivita H. pylori Ag Rapid Test External Control Kit	EDMA	15 01 04 90	Other H. pylori Reagents	Other	N/A	DE/CA09/0170/C33/IVD/038-01
E0330	RecombiLISA Lepto IgM Test; Aria Lepto IgM Test	EDMA	15 01 90 04 00	Leptospira	Other	N/A	DE/CA09/0170/C33/IVD/024-01
E0100	RecombiLISA HAV IgM Test; Aria HAV IgM Test	EDMA	15 02 01 06 00	HAV Antibody IgM	Other	N/A	DE/CA09/0170/C33/IVD/021-02
E0105	RecombiLISA HEV IgM Test; Aria HEV IgM Test	EDMA	15 02 05 06 00	HEV Antibody IgM	Other	N/A	DE/CA09/0170/C33/IVD/022-02
R0203C	OnSite HSV-1 IgG/IgM Rapid Test; Aria HSV-1 IgG/IgM Rapid Test	EDMA	15 04 03 07 00	HSV 1 Antibodies - Total	Other	N/A	DE/CA09/0170/C33/IVD/001-01
R0213C	OnSite HSV-2 IgG/IgM Rapid Test; Aria HSV-2 IgG/IgM Rapid Test	EDMA	15 04 03 10 00	HSV 2 Antibodies - Total	Other	N/A	DE/CA09/0170/C33/IVD/002-01
R0218C	OnSite Duo HSV-1/2 IgG/IgM Rapid Test	EDMA	15 04 03 90	Other HSV Reagents	Other	N/A	DE/CA09/0170/C33/IVD/037-01
P0188H P0188L	Aridia Influenza A Typing Real-Time PCR Test	EDMA	15 04 40 04	Influenza & Para Influenza - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/054
P0060H P0060L	Aridia Dengue Virus Real-Time PCR Test	EDMA	15 04 40 11 00	Dengue Virus - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/033-03
P0061H P0061L	Aridia Dengue Serotyping Real-Time PCR Test	EDMA	15 04 40 11 00	Dengue Virus - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/033-03
P0066H P0066L	Aridia Chikungunya Virus Real-Time PCR Test	EDMA	15 04 40 25	Chikungunya Virus - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/034-01

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P0148H P0148L	Aridia West Nile Virus Real-Time PCR Test	EDMA	15 04 40 26	West Nile Virus - NA Reagent	Other	N/A	DE/CA09/0170/C33/IVD/048
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/CA09/0170/C33/IVD/052
P0070H P0070L	Aridia Zika Virus Real-Time PCR Test	EDMA	15 04 40 90	Other Virology - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/032-04
P0071H P0071L	Aridia Zika/Dengue/CHIK Real-Time PCR Test	EDMA	15 04 40 90	Other Virology - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/032-04
P0182H P0182L	Aridia Rhinovirus/Enterovirus Real-Time PCR Test	EDMA	15 04 40 90	Other Virology - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/032-04
P0187H P0187L	Aridia Influenza A/B & RSV Real-Time PCR Test	EDMA	15 04 40 90	Other Virology - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/032-04
P0218H P0218L	Aridia HSV1/HSV2/T. pallidum Real-Time PCR Test	EDMA	15 04 40 90	Other Virology - NA Reagents	Other	N/A	DE/CA09/0170/C33/IVD/032-04
R0189C	Onsite Adenovirus Ag Rapid Test	EDMA	15 04 80 01	Adenovirus	Other	N/A	DE/CA09/0170/C33/IVD/051
E0310	RecombiLISA Dengue IgM Test; Aria Dengue IgM Test	EDMA	15 04 80 11 00	Dengue Virus	Other	N/A	DE/CA09/0170/C33/IVD/020-02
E0311	RecombiLISA Dengue IgG Test; Aria Dengue IgM Test	EDMA	15 04 80 11 00	Dengue Virus	Other	N/A	DE/CA09/0170/C33/IVD/020-02
E0312	RecombiLISA Dengue Ag Test; Aria Dengue Ag Test	EDMA	15 04 80 11 00	Dengue Virus	Other	N/A	DE/CA09/0170/C33/IVD/020-02
E0315	RecombiLISA CHIK IgM Test; Aria CHIK IgM Test	EDMA	15 04 80 25	Chikungunya Virus	Other	N/A	DE/CA09/0170/C33/IVD/019-02
E0320	RecombiLISA Zika IgM ELISA Test; Aria Zika IgM ELISA Test	EDMA	15 04 80 90 00	Other Viral Antigen/Antibody Detection	Other	N/A	DE/CA09/0170/C33/IVD/031-01
E0170	RecombiLISA Chagas IgG Test; Aria Chagas IgG Test	EDMA	15 05 10 02 00	Chagas	Other	N/A	DE/CA09/0170/C33/IVD/018-02
E0121	RecombiLISA Leishmania Ab Test; Aria Leishmania Ab Test	EDMA	15 05 10 05 00	Leishmania	Other	N/A	DE/CA09/0170/C33/IVD/023-02

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R0190C	Onsite H.pylori Ab Rapid Test; Aria H. pylori Ab Rapid Test	EDMA	15 70 01 02 00	H. pylori - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/007-02
R0191C	Onsite H. pylori Ab Combo Rapid Test; ad-bio H. pylori Ab Combo Rapid Test	EDMA	15 70 01 02 00	H. pylori - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/007-02
R0192C	Onsite H.pylori Ab Combo Rapid Test	EDMA	15 70 01 02 00	H. pylori - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/007-02
R0192S	Onsite H.pylori Ag Rapid Test; Aria H.pylori Ag Rapid Test	EDMA	15 70 01 02 00	H. pylori - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/007-02
R0184C	Onsite Strep A Rapid Test; Aria Strep A Rapid Test	EDMA	15 70 01 03 00	Strep. A - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/014-02
R0184S	Onsite Strep A Rapid Test; ad-bio Strep A Rapid Test; Aria Strep A Rapid Test	EDMA	15 70 01 03 00	Strep. A - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/014-02
R0030C	Onsite Syphilis Ab Rapid Test; ad-bio Syphilis Ab Rapid Test	EDMA	15 70 01 05 00	Syphilis - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/015-02
R0030S	Aria Syphilis Ab Rapid Test	EDMA	15 70 01 05 00	Syphilis - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/015-02
R0031C	Onsite Syphilis Ab Combo Rapid Test; ad-bio Syphilis Ab Combo Rapid Test	EDMA	15 70 01 05 00	Syphilis - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/015-02
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 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0053C	Onsite TB IgG / IgM Combo Rapid Test; ad-bio TB IgG / IgM Combo Rapid Test; Aria IgG / IgM Combo Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0085S	Onsite Gonorrhea Rapid Test; Aria Gonorrhea Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03

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R0130C	Onsite Cholera Ag Rapid Test; Aria Cholera Ag Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0160C	Onsite Typhoid IgG/IgM Rapid Test; Aria Typhoid IgG/IgM Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0161C	Onsite Typhoid IgG/IgM Combo Rapid Test; Aria Typhoid IgG/IgM Combo Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0163C	Onsite Typhoid Ag Rapid Test; Aria Typhoid Ag Rapid Test	EDMA	15 70 01 90 00	Other Bacteriology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/016-03
R0090C	Onsite HAV IgM Rapid Test; ad-bio HAV IgM Rapid Test; Aria HAV IgM Rapid Test	EDMA	15 70 02 90 00	Other Hepatitis Viruses - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/008-02
R0092C	Onsite HAV IgG/IgM Rapid Test; Aria HAV IgG/IgM Rapid Test	EDMA	15 70 02 90 00	Other Hepatitis Viruses - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/008-02
R0095C	Onsite HEV IgM Rapid Test; Aria HEV IgM Rapid Test	EDMA	15 70 02 90 00	Other Hepatitis Viruses - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/008-02
R0110C	Onsite Malaria Pf/Pv Ab Rapid Test; Aria Malaria Pf/Pv Ab Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/012-02
R0111C	Onsite Malaria Pf/Pv Ab Combo Rapid Test; Aria Malaria Pf/Pv Ab Combo Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/012-02
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) - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/012-02
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) - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/012-02
R0114C	Onsite Malaria Pf Ag Rapid Test; Aria Malaria Pf Ag Rapid Test	EDMA	15 70 05 01	Plasmodium (Malaria) - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/012-02
R0121C	Onsite Leishmania IgG/IgM Combo Rapid Test; ad-bio Leishmania IgG/IgM Combo Rapid Test; Aria Leishmania IgG/IgM Combo Rapid Test	EDMA	15 70 05 90	Other Parasites - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/011-02

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R0122S	Onsite Leishmania Ab Rapid Test; Aria Leishmania Ab Rapid Test	EDMA	15 70 05 90	Other Parasites - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/011-02
R0151C	Onsite Filariasis IgG/IgM Combo Rapid Test; Aria Filariasis IgG/IgM Combo Rapid Test	EDMA	15 70 05 90	Other Parasites - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/011-02
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 - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/011-02
R0186C	Onsite RSV Ag Rapid Test	EDMA	15 70 90 02	RSV - RT & POC	Other	N/A	DE/CA09/0170/C33/IVD/050
R0187C	Onsite Influenza A/ B Ag Rapid Test	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/0170/C33/IVD/010-04
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/CA09/0170/C33/IVD/010-04
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 - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/005-02
R0062C	Onsite Duo Dengue Ag - IgG/IgM Combo Rapid Test; ad-bio Duo Dengue Ag - IgG/IgM Combo Rapid Test; Aria Duo Dengue Ag - IgG/IgM Combo Rapid Test	EDMA	15 70 90 07	Dengue - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/005-02
R0063C	Onsite Dengue Ag Rapid Test; ad-bio Dengue Ag Rapid Test; Aria Dengue Ag Rapid Test	EDMA	15 70 90 07	Dengue - Rapid Test	Other	N/A	DE/CA09/0170/C33/IVD/005-02
R0066C	Onsite Chikungunya IgM Combo Rapid Test; ad-bio Chikungunya IgM Combo Rapid Test; Aria Chikungunya IgM Combo Rapid Test	EDMA	15 70 90 00	Other Other Virology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/004-02

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R0069C	Onsite Duo Dengue IgG/IgM - CHIK IgM Rapid Test; Aria Duo Dengue IgG/IgM - CHIK IgM Rapid Test	EDMA	15 70 90 90 00	Other Other Virology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/004-02
R0194C	Onsite Rotavirus Ag Rapid Test; Aria Rotavirus Ag Rapid Test	EDMA	15 70 90 90 00	Other Other Virology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/004-02
R0196C	Onsite Rota/Adeno Ag Rapid Test; Aria Rota/Adeno Ag Rapid Test	EDMA	15 70 90 90 00	Other Other Virology - Rapid Tests	Other	N/A	DE/CA09/0170/C33/IVD/004-02
R0181S	Onsite Influenza A/B Rapid Test with Positivita External Controls	EDMA	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/0170/C33/IVD/010-04
ADX-110	ALTA ELISA Reader	EDMA	21 01 10 01	CH Hardware + accessories + consumables + software	Other	N/A	DE/CA09/0170/C33/IVD/030-01
ADX-120	ALTA Microplate Washer	EDMA	21 01 10 01	CH Hardware + accessories + consumables + software	Other	N/A	DE/CA09/0170/C33/IVD/030-01
RTR-1	ALTA Rapid Test Reader	EDMA	21 02 10 01	IC& II Hardware + accessories + consumables + software	Other	N/A	DE/CA09/0170/C33/IVD/053
R0180C	OnSite COVID-19 IgG/IgM Rapid Test; Aria COVID-19 IgG/IgM Rapid Test	EDMA	15 04 80 19	Coronavirus	Other	N/A	DE/CA09/0170/C33/IVD/055