



DECLARATION OF CONFORMITY

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- 1) Manufacturer: **CTK Biotech, Inc**
Address: **13855 Stowe Dr. Poway, CA 92064, USA**
- 2) European authorized representative: **MDSS**
Address: **Schiffgraben 41, 30175 Hannover, Germany**
- 3) Product(s)
 - **Rapid tests**
 - **ELISA**
 - **Rapid test external controls***see appendix for individual product list*

- 4) The product(s) described above is in conformity with:

Title	Document No.	Date of issue
<i>In vitro</i> Diagnostic Medical Devices Directive	98/79/EC	1998-10-27

- 5) Additional information

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

This declaration of conformity and the products above are issued under the sole responsibility of CTK Biotech Inc.

San Diego, USA; 2020-03-11

Jiayi Zhang
Regulatory Affairs Specialist
CTK Biotech, Inc.

Appendix

List of devices

Device group: **OnSite Brand Rapid Test**

Device name	Type/ model/ref number	EDMS-code	Risk Class	First date of CE-marking
Infectious diseases				
Onsite Syphilis Ab Rapid Test	R0030C	15700105	IVD-Other	2006-06-08
Onsite Syphilis Ab Rapid Test (strip)	R0030S	15700105	IVD-Other	2006-06-08
Onsite Syphilis Ab Combo Rapid Test	R0031C	15700105	IVD-Other	2006-06-08
Onsite TB IgG / IgM Rapid Test	R0051C	15700190	IVD-Other	2006-06-08
Onsite TB IgG / IgM Combo Rapid Test	R0053C	15700190	IVD-Other	2006-06-08
Onsite Dengue IgG/IgM Combo Rapid Test	R0061C	15709007	IVD-Other	2006-06-08
Onsite Duo Dengue Ag - IgG/IgM Combo Rapid Test	R0062C	15709007	IVD-Other	2011-03-04
Onsite Dengue Ag Rapid Test	R0063C	15709007	IVD-Other	2011-03-04
Onsite Chikungunya IgM Combo Rapid Test	R0066C	15709090	IVD-Other	2007-02-09
Onsite Duo Dengue IgG/IgM-CHIK IgM Rapid Test	R0069C	15709090	IVD-Other	2009-06-30
Onsite Gonorrhoea Rapid Test (strip)	R0085S	15700190	IVD-Other	2006-06-08
Onsite HAV IgM Rapid Test	R0090C	15700290	IVD-Other	2006-06-08
Onsite HAV IgG/IgM Rapid Test	R0092C	15700290	IVD-Other	2006-06-08
Onsite HEV IgM Rapid Test	R0095C	15700290	IVD-Other	2011-06-24
Onsite Malaria Pf/Pv Ab Rapid Test	R0110C	15700501	IVD-Other	2006-06-08
Onsite Malaria Pf/Pv Ab Combo Rapid Test	R0111C	15700501	IVD-Other	2006-06-08
Onsite Malaria Pf/Pv Ag Rapid Test	R0112C	15700501	IVD-Other	2006-06-08
Onsite Malaria Pf/Pan Ag Rapid Test	R0113C	15700501	IVD-Other	2007-02-09
Onsite Malaria Pf Ag Rapid Test	R0114C	15700501	IVD-Other	2007-02-09
Onsite Leishmania IgG/IgM Combo Rapid Test	R0121C	15700590	IVD-Other	2006-06-08
Onsite Leishmania Ab Rapid Test (strip)	R0122S	15700590	IVD-Other	2006-06-08

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Device name	Type/ model/ref number	EDMS-code	Risk Class	First date of CE-marking
Onsite Filariasis IgG/IgM Combo Rapid Test	R0151C	15700590	IVD-Other	2006-06-08
Onsite Chagas Ab Combo Rapid Test	R0171C	15700590	IVD-Other	2006-06-08
OnSite COVID-19 IgG/IgM Rapid Test	R0180C	15048019	IVD-Other	2020-03-11
Onsite Influenza A/B Rapid Test with Positivita External Controls	R0181S	15709004	IVD-Other	2019-10-03
Onsite Strep A Rapid Test	R0184C	15700103	IVD-Other	2015-07-06
Onsite Strep A Rapid Test (strip)	R0184S	15700103	IVD-Other	2006-06-08
Onsite RSV Ag Rapid Test	R0186C	15709002	IVD-Other	2019-05-22
Onsite Influenza A/B Ag Rapid Test	R0187C	15709004	IVD-Other	2019-05-22
Onsite Influenza A/B Rapid Test (strip)	R0187S	15709004	IVD-Other	2006-06-08
Onsite Adenovirus Ag Rapid Test	R0189C	15048001	IVD-Other	2019-05-22
Onsite H.pylori Ab Rapid Test	R0190C	15700102	IVD-Other	2006-06-08
Onsite H. pylori Ab combo Rapid Test	R0191C	15700102	IVD-Other	2006-06-08
Onsite H.pylori Ag Rapid Test	R0192C	15700102	IVD-Other	2006-06-08
Onsite H.pylori Ag Rapid Test (strip)	R0192S	15700102	IVD-Other	2006-06-08
Onsite Rotavirus Ag Rapid Test	R0194C	15709090	IVD-Other	2006-06-08
Onsite Rota/Adeno Ag Rapid Test	R0196C	15709090	IVD-Other	2013-03-28
OnSite HSV-1 IgG/IgM Rapid Test	R0203C	15040307	IVD-Other	2015-07-24
OnSite HSV-2 IgG/IgM Rapid Test	R0213C	15040310	IVD-Other	2015-07-24
OnSite Duo HSV-1/2 IgG/IgM Rapid Test	R0218C	15040390	IVD-Other	2018-03-21
Gastrointestinal Infection				
Onsite Cholera Ag Rapid Test	R0130C	15700190	IVD-Other	2006-06-08
Onsite Typhoid IgG/IgM Rapid Test	R0160C	15700190	IVD-Other	2006-06-08
Onsite Typhoid IgG/IgM Combo Rapid Test	R0161C	15700190	IVD-Other	2006-06-08
Onsite Typhoid Ag Rapid Test	R0163C	15700190	IVD-Other	2009-06-30
Biomarker				
Onsite FOB rapid test (50ng/ml) Rapid Test	R2010C	12700390	IVD-Other	2006-06-08

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Device name	Type/ model/ref number	EDMS-code	Risk Class	First date of CE-marking
Onsite FOB-Hi rapid test (25ng/ml) Rapid Test	R2011C	12700390	IVD-Other	2006-06-08
Onsite Troponin I Rapid Test	R3001C	12701303	IVD-Other	2006-06-08
Onsite Troponin I Combo Rapid Test	R3002C	12701303	IVD-Other	2006-06-08
Onsite RF Rapid Test	R0310C	12701190	IVD-Other	2014-09-02
Fertility				
Onsite hCG Urine Rapid Test	R1000C	12700502	IVD-Other	2006-06-08
Onsite hCG Urine Rapid Test (strip)	R1000S	12700502	IVD-Other	2006-06-08
Onsite hCG Combo Rapid Test	R1001C	12700502	IVD-Other	2006-06-08
Onsite hCG Combo Rapid Test (strip)	R1001S	12700502	IVD-Other	2006-06-08

Device group: **ELISA TEST**

Device name	Type/ model/ref number	EDMS-code	Risk Class	First date of -marking
RecombiLISA HAV IgM ELISA	E0100	15020106	IVD-Other	2006-06-08
RecombiLISA Leishmania Ab ELISA	E0121	15051005	IVD-Other	2006-06-08
RecombiLISA Chagas IgG ELISA	E0170	15051002	IVD-Other	2006-06-08
RecombiLISA Dengue IgM ELISA	E0310	15048011	IVD-Other	2006-06-08
RecombiLISA Dengue IgG ELISA	E0311	15048011	IVD-Other	2006-06-08
RecombiLISA CHIK IgM ELISA	E0315	15048025	IVD-Other	2007-02-09
RecombiLISA Dengue Ag ELISA	E0312	15048011	IVD-Other	2011-03-04
RecombiLISA Zika IgM ELISA	E0320	15048090	IVD-Other	2017-05-23
RecombiLISA Lepto IgM ELISA	E0330	15019004	IVD-Other	2011-06-24
RecombiLISA Syphilis Ab ELISA	E0610	15010303	IVD-Other	2006-06-08
CTK hCG ELISA	E1000	12050205	IVD-Other	2018-03-21
RecombiLISA Total T3 ELISA	E1010	12040105	IVD-Other	2011-06-24
RecombiLISA Free T3 ELISA	E1011	12040101	IVD-Other	2017-08-10
CTK Total Triiodothyronine (T3) ELISA	E1015	12040105	IVD-Other	2019-05-22

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CTK fT3 ELISA	E1016	12040101	IVD-Other	2019-05-22
RecombiLISA Total T4 ELISA	E1020	12040107	IVD-Other	2011-06-24
RecombiLISA Free T4 ELISA	E1021	12040102	IVD-Other	2017-08-10
CTK Total Thyroxine (T4) ELISA	E1025	12040107	IVD-Other	2019-05-22
CTK fT4 ELISA	E1026	12040102	IVD-Other	2019-05-22
RecombiLISA TSH ELISA	E1030	12040111	IVD-Other	2011-06-24
CTK TSH ELISA	E1035	12040111	IVD-Other	2019-03-19
RecombiLISA HEV IgM ELISA	E0105	15020506	IVD-Other	2011-06-24
CTK PRL ELISA	E1080	12050108	IVD-Other	2018-03-21
CTK LH ELISA	E1090	12050105	IVD-Other	2018-03-21
CTK FSH ELISA	E1100	12050104	IVD-Other	2018-03-21
CTK Testosterone ELISA	E1210	12050110	IVD-Other	2018-03-21
CTK Progesterone ELISA	E1220	12050106	IVD-Other	2018-03-21
CTK Estradiol (E2) ELISA	E1230	12050103	IVD-Other	2018-03-21
CTK Vitamin D (Total) ELISA	E8010	12070204	IVD-Other	2018-03-21
CTK Vitamin B12 ELISA	E8030	12050104	IVD-Other	2018-03-21

Device group: **External Control Kit**

Device name	Type/ model/ref number	EDMS-code	Risk Class	First date of -marking
Infectious Diseases				
Positivita Influenza A/B Rapid Test External Control Kit	C0187	12705050	IVD-Other	2016-08-10
Positivita H. pylori Ag Rapid Test External Control Kit	C0192	15010490	IVD-Other	2018-03-21