

## DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): **Cliniqa Corporation**  
Address: **495 Enterprise Street, San Marcos, CA 92078, USA**  
and

2) European authorized representative: **Cepartner4U BV**,  
Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;  
(on product labels printed as:  
Cepartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS [www.cepartner4u.eu](http://www.cepartner4u.eu)

3) Product(s) (name, type or model/batch number, etc.):

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|---|
| <ul style="list-style-type: none"><li>- <b>Protein Calibration sets, Controls, Standards and Reagents</b></li><li>- <i>see appendix</i></li></ul> |
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4) The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
<i>In vitro</i> Diagnostic Medical Devices Directive	98/79/EC

5) Additional information (conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking:

Low risk devices – IVD Directive, Annex III excluding self-testing section 6

List B devices – IVD Directive Annex IV; Notified Body: NSAI, # 0050; Certificate number: 304.017  
and 304.1004/0

San Marcos, CA 92078;

2021-06-01

(Place & date of issue (yyyy-mm-dd))

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Dawn Gast, Site Director Cliniqa Corporation

(Name; function and signature of manufacturer)

## Appendix

Date: 2018-25-16

Device name	Type/ model/ref number	Risk class	First date of CE- compliance	EDMS code
<b>Calibration / Verifiers</b>				
<b>Registration number: NL-CA002-26902</b>				
LiniCAL Cardiac CalVer for Beckman Systems, Level A-E	98232	Low	2020-02-01	12 50 01 07 00
LiniCAL Cardiac CalVer for Roche Systems, Level A-F	98505	Low	2020-02-01	12 50 01 07 00
LiniCAL Calibration Verifier for Beckman Coulter AU Systems Protein 2, Level A-E	98302	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier for Beckman Coulter AU Systems Protein 3, Level A-E	98303	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier for Roche Systems, Protein 1, Levels A-F	98501	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier for Roche Systems Protein 2, Level A-E	98502	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier, for Roche Systems Protein 3, Level A-F	98503	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier for Roche Systems Protein 4, Levels A-F	98504	Low	2020-02-01	12 50 01 05 00
LiniCAL Calibration Verifier for Ortho Systems Cardiac	98750	Low	2020-05-12	12 50 01 07 00
Calibration Vérifier RF/CRP BCI Synchron	98228	Low	2003-11-28	12 50 03 05 00
Fructosamine Calibrator	R85321	Low	2009-05-01	11 50 03 02 00
Multi-Analyte Serum Calibrator	R60010	Low	2009-05-01	11 50 01 01 00
<b>Controls</b>				
<b>Registration number Low Risk : NL-CA002-26904</b>				
<b>ImmuTROL</b>				
ImmuTROL Serum Protein Control Level 1	91101	Low	2003-11-28	12 50 01 06 00
ImmuTROL Serum Protein Control Level 2	91102	Low	2003-11-28	12 50 01 06 00
ImmuTROL Serum Protein Control Level 3	91103	Low	2003-11-28	12 50 01 06 00
ImmuTROL Serum Protein Controls Tri-Level (Levels 1, 2 & 3) 2 x 3 x 3 mL	91104	Low	2003-11-28	12 50 01 06 00
ImmuTROL Serum Protein Controls Bi-Level (Levels 1 & 3) 3 x 2 x 3 mL	91105	Low	2003-11-28	12 50 01 06 00
<b>hsCRP</b>				
hsCRP Serum Protein Control Level 1	91201	Low	2003-11-28	12 50 01 06 00
hsCRP Serum Protein Control Level 2	91202	Low	2003-11-28	12 50 01 06 00
hsCRP Serum Protein Control Level 3	91203	Low	2003-11-28	12 50 01 06 00
hsCRP Serum Protein Controls Tri-Level (Levels 1, 2 & 3)	91204	Low	2003-11-28	12 50 01 06 00
<b>Cardiac Marker</b>				
Cardiac Marker Control Complete + TnI Level 1	91481	Low	2010-09-28	12 50 01 08 00
Cardiac Marker Control Complete + TnI Level 2	91482	Low	2010-09-28	12 50 01 08 00
Cardiac Marker Control Complete +TnI Level 3	91483	Low	2010-09-28	12 50 01 08 00
Cardiac Marker Control Complete + TnT Level 1	91490	Low	2010-09-28	12 50 01 08 00
Cardiac Marker Control Complete + TnT Level 2	91491	Low	2010-09-28	12 50 01 08 00

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Cardiac Marker Control Complete +TnT Level 3	91492	Low	2010-09-28	12 50 01 08 00
Cardiac Marker Control for i-STAT Level 1	06F12-09	Low	2007-04-12	12 50 01 08 00
Cardiac Marker Control for i-STAT Level 2	06F12-10	Low	2007-04-12	12 50 01 08 00
Cardiac Marker Control for i-STAT Level 3	06F12-11	Low	2007-04-12	12 50 01 08 00
Cardiac Marker Control for i-STAT Tri-Level (Levels 1, 2 & 3)	06F12-12	Low	2007-04-12	12 50 01 08 00
Cardiac Marker Controls VS Tri-Level (Levels 1, 2 & 3)	91474	Low	2007-04-12	12 50 01 08 00
Cardiac Marker Control (CK-MB/Myoglobin/Troponin I), (Levels 1 & 2)	91405	Low	2009-02-20	12 50 01 08 00
Cardiac Marker Control (NT-proBNP, D-Dimer) (Levels 1 & 2)	91435	Low	2009-02-20	12 50 01 08 00
Cardiac Marker Control CS Tri level kit (Levels 1, 2 & 3) 2 x 3 x 3 mL	91444	Low	2015-12-01	12 50 01 08 00
Cardiac Marker Control CS Tri level kit (Levels 1,2 & 3) 1 x 3 x 3 mL	91449	Low	2015-12-01	12 50 01 08 00
Liquid QC® cTnl Control for Minicare I-20, Bi-Level	83352	Low	2016-04-13	12 50 01 08 00
Liquid QC Cardiac Marker Controls for the Nexus IB10	IVR-IB66	Low	2020-09-02	12 50 01 08 00
<b>Urinalysis Controls</b>				
DipStrip Urinalysis Control, Bi-Level (Levels 1 & 2)	97201	Low	2009-02-20	11 50 02 06 00
DropStrip Urinalysis Control, Bi-Level (Levels 1 & 2)	97202	Low	2009-02-20	11 50 02 06 00
MicroStrip Urinalysis Control, Bi-Level (Levels 1 & 2)	97203	Low	2009-02-20	11 50 02 06 00
DipScopics Urinalysis Control, Bi-Level (Levels 1 & 2)	97204	Low	2009-02-20	11 50 02 06 00
<b>Urine Chemistry Controls</b>				
Urine Chemistry Control, Bi-Level (Levels 1 & 2) 6 x 2 x 10 mL	97105	Low	2009-02-20	11 50 02 06 00
Urine Chemistry Control, Bi-Level (Levels 1 & 2)	97109	Low	2009-02-20	11 50 02 06 00
<b>COVID-19 Control</b>				
CoV-2 IgG Control, Bi-Level (Levels 1&2) 2x3x3 mL	91494	Low	2020-09-22	11 50 90 90 00
CoV-2 Antigen Control, Bi-Level (Levels 1&2) 2x3x3 mL	91496	Low	2020-06-01	11 50 90 90 00
<b>Other controls</b>				
Lipid Control Level 1	91501	Low	2011-02-07	12 50 01 90 00
Lipid Control Level 2	91502	Low	2011-02-07	12 50 01 90 00
Lipid Control Bi-Level (Levels 1 & 2)	91505	Low	2011-02-07	12 50 01 90 00
Alcohol / Ammonia Control Level 1	95501	Low	2007-01-29	12 50 01 90 00
Alcohol / Ammonia Control Level 2	95502	Low	2007-01-29	12 50 01 90 00
Alcohol / Ammonia Control Bi- Level (Level 1 & 2)	95505	Low	2007-01-29	12 50 01 90 00
Diabetes Control, Bi-Level (Levels 1 & 2) 3 x 2 x 0.5 mL	91815	Low	2008-05-15	11 50 02 05 00
Diabetes Control, Bi-Level (Levels 1 & 2) 1 x 2 x 0.5 mL	91819	Low	2008-05-15	11 50 02 05 00
Whole Blood Ethanol Control Level 1	93211	Low	2009-02-20	11 50 02 90 00
Whole Blood Ethanol Control Level 2	93212	Low	2009-02-20	11 50 02 90 00
Whole Blood Volatiles Control Level 1	93221	Low	2009-02-20	11 50 02 90 00
Whole Blood Volatiles Control Level 2	93222	Low	2009-02-20	11 50 02 90 00
Assayed Control Serum Level 1	R83082	Low	2009-05-01	12 50 01 06 00
Assayed Control Serum Level 2	R83083	Low	2009-05-01	12 50 01 06 00
Vitamin D Control Bi-Level	83638	Low	2017-10-30	11 50 02 90 00

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NEPHROCHECK Control Levels 1&2	83938	Low	2021-02-28	11 50 02 90 00
NEPHROCHECK Method Validation	83940	Low	2021-02-28	11 50 02 90 00
<b>Tumor Marker Control</b>				
<b>Registration number List B: NL-CA002-14656</b>				
Tumor Marker Control Level 1	91301	High, List B Cert.Number : 304.017	2005-03-08	12 50 01 10 00
Tumor Marker Control Level 2	91302	High, List B Cert.Number : 304.017	2005-03-08	12 50 01 10 00
Tumor Marker Control Level 3	91303	High, List B Cert.Number : 304.017	2005-03-08	12 50 01 10 00
Tumor Marker Controls Tri-Level (Levels 1, 2 & 3) 2 x 3 x 3 mL	91304	High, List B Cert.Number : 304.017	2005-03-08	12 50 01 10 00
<b>Immunoassay Controls</b>				
<b>Registration number List B: NL-CA002-26903</b>				
Immunoassay Control Level 1	94101	High; list B Cert.Number :304.1004	2009-09-16	12 50 01 10 00
Immunoassay Control Level 2	94102	High; list B Cert.Number :304.1004	2009-09-16	12 50 01 10 00
Immunoassay Control Level 3	94103	High; list B Cert.Number :304.1004	2009-09-16	12 50 01 10 00
Immunoassay Controls Tri-Level (Levels 1, 2 & 3) 2 x 3 x 5 mL	94104	High; list B Cert.Number :304.1004	2009-09-16	12 50 01 10 00
Immunoassay Controls Tri-Level (Levels 1, 2 & 3) 1 x 3 x 5 mL	94109	High; list B Cert.Number :304.1004	2009-09-16	12 50 01 10 00
<b>Standards</b>				
<b>Registration number Low Risk: NL-CA002-26905</b>				
Ammonia Standard	R85406	Low	2009-05-01	11 50 03 02 00
<b>Reagents</b>				
<b>Registration number Low Risk : NL-CA002-26906</b>				
ALT(GPT) Reagent 20 x 3 mL	R85309	Low	2009-05-01	11 01 01 03 00
ALT(GPT) Reagent 20 x 6.5 mL	R85122	Low	2009-05-01	11 01 01 03 00
ALT(GPT) Reagent 10 x 20 mL	R80023	Low	2009-05-01	11 01 01 03 00
ALT(GPT) Reagent 10 x 50 mL	R82055	Low	2009-05-01	11 01 01 03 00
Ammonia Reagent 10 x 6.5 mL	R85444	Low	2009-05-01	11 03 01 01 00
Ammonia Reagent 8 x 20 mL	R85446	Low	2009-05-01	11 03 01 01 00
BUN Slow Rate Reagent	R85139	Low	2009-05-01	11 02 01 04 00
Calcium Liquid Reagent	R85188	Low	2009-05-01	11 03 01 03 00
Cholesterol Reagent with Standard 10 x 50 mL	R80035	Low	2009-05-01	11 02 01 05 00
CK NADP Imidazole Reagent 20 x 6.5 mL	R85191	Low	2009-05-01	11 01 01 13 00

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CK NADP Reagent 20 x 3 mL	R85306	Low	2011-02-07	11 01 01 13 00
CK NADP Reagent 20 x 6.5 mL	R85119	Low	2011-02-07	11 01 01 13 00
CO <sub>2</sub> Low NADH Reagent	R85368	Low	2009-05-01	11 03 01 90 00
Creatinine Reagent 2 x 100 mL	R85559	Low	2011-02-07	11 01 01 90 00
G-6-P/NAD +Buffer 5 x 525 mL	R85407	Low	2011-02-07	11 90 01 01 00
GGT Reagent 20 x 3 mL	R85307	Low	2009-05-01	11 01 01 16 00
Glucose UV Reagent 10 x 50 mL	R80036	Low	2009-05-01	11 02 01 13 00
Glucose UV Reagent 4 x 1000 mL	R85411	Low	2009-05-01	11 02 01 13 00
HDL Cholesterol Reagent	R82051	Low	2009-05-01	11 02 01 15 00
Inorganic Phosphorus Reagent R1 4 x 125 mL	R85562	Low	2011-02-07	11 03 01 08 00
LDH-L Reagent 10 x 20 mL	R82045	Low	2009-05-01	11 02 01 21 00
LDH-P Reagent 20 x 3 mL	R85312	Low	2011-02-07	11 02 01 21 00
Magnesium Liquid Reagent	R85207	Low	2009-05-01	11 03 01 70 00
Multiplier II	R85273	Low	2009-05-01	11 90 01 01 00
Phosphorous Reagent 4 x 120 mL	R85168	Low	2009-05-01	11 03 01 08 00
Triglyceride Liquid Reagent 2 x 80 mL + 2 x 40 mL	R85457	Low	2009-05-01	11 02 01 31 00
Triglycerides Liquid Reagent 10 x 7 mL + 10 x 3.5 mL	R85553	Low	2011-02-07	11 02 01 31 00
Hemoglobin A1c Calibrators, Levels 1-4, Lyophilized 4 x 0.5 mL	85962	Low	2013-03-05	11 02 01 14 00

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