Certificate of Registration

In accordance with European Communities Council Directive 98/79/EC as amended, concerning In Vitro Medical Devices as transposed into European national law by the member states.

We hereby declare that:

- **An examination has been made of this organisation's Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.**
- **The EU Authorised Representative contract has been fulfilled.**
- **Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.**

Therefore, these devices have met the requirements of the council directive and the CE mark may be applied to the products listed below.

Certificate No: CE/USA/2015/07/69	Issue Date: 01st September 2020	Expiry Date: 31st August 2021

Legal Manufacturer	EU Authorised Representative (EC REP)
Kamiya Biomedical Company 12779 Gateway Drive S., Tukwila, WA 98168, USA	Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta.

Product Details, Names or Trade Names	MCCAA Device Registration Reference(s)
K-Assay Assay Controls for clinical chemistry analysers	DVC-MT-17-07-000013
K-Assay Assay reagents for clinical chemistry analysers	DVC-MT-17-07-000014
K-Assay Assay calibrators for clinical chemistry analysers	DVC-MT-17-07-000015

Competent Authority
Malta Competition and Consumer Affairs Authority (MCCAA) Mizzi House, National Road, Blata I-Bajda, HMR 9010 Malta. Tel: +356 2395 2000 Email: info@mccaa.org.mt

This certificate is issued by:	Authorised Signature:
Advena Limited **Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013.** **Malta. Tel: +44 1926 800153 Email: info@advenamedical.com** **Registered in Malta No. C 76865**	*A. Kirby* **Anthony Kirby - Managing Director (Malta)**

This certificate is subject to the organisation maintaining their documentation in compliance with the directive stated in this certificate.

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

Declaration of Conformity for Assay Controls

Version	Compiled By	Date	Description
1.0	Colin Getty	2017-01-27	First Issue
1.1	Colin Getty	2017-09-13	Add 1 product
1.2	Colin Getty	2018-01-18	Update address
1.3	Colin Getty	2018-08-23	Add D-Dimer Control
1.4	Colin Getty	2018-12-27	Remove 2 products, add 4 products, update codes
1.5	Colin Getty	2019-06-04	Add 1 product
1.6	Satsuki Yoshimura	2020-05-20	Add 2 products, change GIVD code to GMDN code
1.7	Satsuki Yoshimura	2020-09-09	Remove 1 product, add 2 products

European Communities Council Directive 98/79/EC Concerning In-Vitro Diagnostic Medical Devices, as amended, and as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Assay controls for clinical chemistry analyzers
Legal Manufacturer: (Name on Label)	KAMIYA BIOMEDICAL COMPANY 12779 Gateway Drive S. Tukwila, WA 98168 USA
Variants:	As per ANNEX – Product Listings
Intended Use:	Clinical chemistry analyzer IVD assay controls for measuring serum proteins. For professional use.
IVD Directive Category:	NOT Annex II and NOT self-test devices
Notified Body:	Not Applicable
Applicable Standards:	ISO 13485:2016, ISO 18113-2:2011, ISO 15223-1:2016, ISO 14971:2019
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Annex III. re Article 9, paragraph 5 of Directive 98/79/EC OR AS APPLICABLE

Signed: Satsuki Yoshimura Name: Satsuki Yoshimura

Position: Management Representative Date: September 9, 2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labeling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

ANNEX – Control Product Listing/Schedule

Product Name / Description	Catalog Reference	GMDN Code
K-ASSAY® Apolipoprotein Control	K112C-2M K112C-4M K112C-L1 K112C-L2	43708
K-ASSAY® ASO/RF/CRP Control	K55C-2M K55C-4M	53594
K-ASSAY® Beta-2 Microglobulin / Ferritin - Serum/Plasma Control	K283C-2M K283C-4M	38214
K-ASSAY® Beta-2 Microglobulin Urine Control	K284C-2M K284C-4M	38214
K-ASSAY® High-Sensitive CRP Control	K80C-4M	41839
K-ASSAY® Cystatin C Control	K100C-2M K100C-4M	48175
K-ASSAY® D-Dimer Control	K92C-2M K92C-4M	47347
K-ASSAY® High-Sensitive D-Dimer Control	K115C-10M	47347
K-ASSAY® Factor XIII Control (2 names for same product) K-ASSAY® Coagulation Control	K135C-10M K204C-10M	56054
K-ASSAY® Plasma FDP Control	K131C-10M	56110
K-ASSAY® Serum FDP Control	K322C-10M	56110
K-ASSAY® Urine FDP Control	K327C-10M	56110
K-ASSAY® H. Pylori Control	K242C-2M K242C-4M	51024
K-ASSAY® Hemoglobin A1c Control	K29C-4M K312C-4M	44435
K-ASSAY® Insulin Control	K73C-2M K73C-4M	42092
K-ASSAY® KL-6 Control	K252C-2M K252C-4M	60556
K-ASSAY® Liquid ITA Control	K49C-2M K49C-4M	53594
K-ASSAY® Lp(a) Control	K114C-2M K114C-4M	41418
K-ASSAY® Microalbumin Urine Control	K37C-4M K37C-SAM	53478
K-ASSAY® RF / ASO Liquid Control	K125C-2M K125C-4M	53594
K-ASSAY® Total IgE Control	K94C-2M K94C-4M	37763
K-ASSAY® Vitamin C Control	KT-75002 KT-75003	54462

End of Annex

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

Declaration of Conformity for Assay Reagents

Version	Compiled By	Date	Description
1.0	Colin Getty	2017-01-27	First Issue
1.1	Colin Getty	2017-09-13	Add 1 product
1.2	Colin Getty	2018-01-18	Update address
1.3	Colin Getty	2018-12-27	Remove 1 product, add 1 product, update codes
1.4	Colin Getty	2019-06-04	Add 6 products
1.5	Satsuki Yoshimura	2020-05-20	Add 3 products, change GIVD code to GMDN code
1.6	Satsuki Yoshimura	2020-09-09	Remove 1 product, add 2 products

European Communities Council Directive 98/79/EC Concerning In-Vitro Diagnostic Medical Devices, as amended, and as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Assay reagents for clinical chemistry analyzers
Legal Manufacturer: (Name on Label)	KAMIYA BIOMEDICAL COMPANY 12779 Gateway Drive S. Tukwila, WA 98168 USA
Variants:	As per ANNEX – Product Listings
Intended Use:	Clinical chemistry analyzer IVD assay reagents for measuring serum proteins. For professional use.
IVD Directive Category:	NOT Annex II and NOT self-test devices
Notified Body:	Not Applicable
Applicable Standards:	ISO 13485:2016, ISO 18113-2:2011, ISO 15223-1:2016, ISO 14971:2019
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Annex III. re Article 9, paragraph 5 of Directive 98/79/EC OR AS APPLICABLE

Signed: Satsuki Yoshimura Name: Satsuki Yoshimura

Position: Management Representative Date: September 9, 2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labeling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

ANNEX – Assay Reagent Product Listing/Schedule

Product Name / Description	Catalog Number	GMDN Code
K-ASSAY® Alpha-1 AG Reagent	KAI-021	53607
K-ASSAY® Alpha-1 AT Reagent	KAI-001	53605
K-ASSAY® Alpha-1 Microglobulin Reagent	KAI-056	53924
K-ASSAY® Apo AI Reagent	KAI-002	53444
K-ASSAY® Apo AII Reagent	KAI-003	53446
K-ASSAY® Apo B Reagent	KAI-004	53448
K-ASSAY® Apo B (L) Reagent	KAI-024	
K-ASSAY® Apo CII Reagent	KAI-005	53450
K-ASSAY® Apo CIII Reagent	KAI-006	53452
K-ASSAY® Apo E Reagent	KAI-007	53459
K-ASSAY® ASO (WHO) Reagent	KAI-078	51746
K-ASSAY® ASO (WHO) Reagent (XXL)	KAI-078-B1 KAI-078-B2	
K-ASSAY® Beta-2 Microglobulin Reagent	KAI-280	53930
K-ASSAY® Complement C3 Reagent	KAI-009	53686
K-ASSAY® Complement C4 Reagent	KAI-010	53693
K-ASSAY® CRP Reagent	KAI-026	53707
K-ASSAY® CRP (L) Reagent	KAI-033	
K-ASSAY® CRP (3) Reagent	KAI-082	53707
K-ASSAY® CRP (3) Reagent (XXL)	KAI-082-B1 KAI-082-B2	
K-ASSAY® hsCRP	KAI-160	53707
K-ASSAY® Cystatin C Reagent	KAI-073	48177
K-ASSAY® Cystatin C (L) Reagent	KAI-074	
K-ASSAY® D-Dimer Reagent	KAI-090	47349
K-ASSAY® D-Dimer Reagent (XXL)	KAI-090-B1 KAI-090-B2	
K-ASSAY® High-Sensitive D-Dimer Reagent	KAI-102	47349
K-ASSAY® Factor XIII Reagent	KAI-105	56055
	KAI-205	
K-ASSAY® Plasma FDP Reagent	KAI-111	56111
K-ASSAY® Plasma FDP Reagent (XXL)	KAI-111-B1 KAI-111-B2	
K-ASSAY® Serum FDP Reagent	KAI-320	56111
K-ASSAY® Urine FDP Reagent	KAI-325	56111
K-ASSAY® Ferritin Reagent	KAI-095	53719
K-ASSAY® Ferritin Reagent (XXL)	KAI-095-B1 KAI-095-B2	
K-ASSAY® Ferritin (L) Reagent	KAI-046	
K-ASSAY® Fibrinogen Reagent + Calibrator	KAI-035	56000
K-ASSAY® Fibrinogen Reagent	KAI-135	
K-ASSAY® Fibrinogen (L) Reagent	KAI-088	
K-ASSAY® H. Pylori Reagent	KAI-240	51025
K-ASSAY® H. Pylori Reagent (XXL)	KAI-240-B1 KAI-240-B2	
K-ASSAY® Haptoglobin Reagent	KAI-022	53738

(ANNEX continued on next page)

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

ANNEX – Assay Reagent Product Listing/Schedule (continued)

Product Name / Description	Catalog Number	GMDN Code
K-*ASSAY*® Hemoglobin A1c Reagent	KAI-196	53316
K-*ASSAY*® Hemoglobin A1c Hemolysis Reagent	KAI-195	
K-*ASSAY*® Hemoglobin A1c (L) Reagent	KAI-197	
K-*ASSAY*® Hemoglobin A1c Reagent	KAI-310	53316
K-*ASSAY*® Hemoglobin A1c Reagent (XXL)	KAI-310-B	
K-*ASSAY*® IgA Reagent	KAI-013	53759
K-*ASSAY*® Total IgE Reagent	KAI-092	53778
K-*ASSAY*® Total IgE Reagent (XXL)	KAI-092-B KAI-092-B1 KAI-092-B2	
K-*ASSAY*® IgG Reagent	KAI-014	53786
K-*ASSAY*® IgM Reagent	KAI-015	53794
K-*ASSAY*® Insulin Reagent	KAI-040	54239
K-*ASSAY*® Insulin Reagent (XXL)	KAI-071-B KAI-071-B1 KAI-071-B2	
K-*ASSAY*® Insulin (L) Reagent	KAI-071	
K-*ASSAY*® KL-6 Reagent	KAI-250	60557
K-*ASSAY*® Lp(a) Reagent	KAI-044	53442
K-*ASSAY*® Lp(a) (L) Reagent	KAI-017	
K-*ASSAY*® Microalbumin Reagent	KAI-019	53479
K-*ASSAY*® Microalbumin Reagent (XXL)	KAI-019-B1 KAI-019-B2	
K-*ASSAY*® Microalbumin (L) Reagent	KAI-057	
K-*ASSAY*® Microalbumin Reagent	KAI-319-B1 KAI-319-B2	
K-*ASSAY*® Prealbumin Reagent	KAI-053	53959
K-*ASSAY*® RF Reagent	KAI-031	55113
K-*ASSAY*® RF Reagent (XXL)	KAI-031-B1 KAI-031-B2	
K-*ASSAY*® RF Reagent (Ver.2)	KAI-230	55113
K-*ASSAY*® Transferrin Reagent	KAI-023	53994
K-*ASSAY*® Transferrin (L) Reagent	KAI-101	
K-*ASSAY*® UIBC (Unsaturated Iron Binding Capacity) Reagent	KAI-300	58197
K-*ASSAY*® UIBC (L) (Unsaturated Iron Binding Capacity) Reagent	KAI-301	
K-*ASSAY*® Vitamin C Reagent	KT-75000 KT-75010	54463
K-*ASSAY*® Vitamin C Reagent + Calibrator	KT-75005 KT-75006	54463

End of Annex

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

Declaration of Conformity for Assay Calibrators

Version	Compiled By	Date	Description
1.0	Colin Getty	2017-01-27	First Issue
1.1	Colin Getty	2017-09-13	Add 1 product
1.2	Colin Getty	2018-01-18	Update address
1.3	Colin Getty	2018-12-27	Remove 1 product, add 2 products, update codes
1.4	Colin Getty	2019-06-04	Add 2 products
1.5	Satsuki Yoshimura	2020-05-20	Add 3 products, change GIVD code to GMDN code
1.6	Satsuki Yoshimura	2020-09-09	Remove 1 product, add 2 products

European Communities Council Directive 98/79/EC Concerning In-Vitro Diagnostic Medical Devices, as amended, and as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Assay calibrators for clinical chemistry analyzers
Legal Manufacturer: (Name on Label)	KAMIYA BIOMEDICAL COMPANY 12779 Gateway Drive S. Tukwila, WA 98168 USA
Variants:	As per ANNEX – Product Listings
Intended Use:	Clinical chemistry analyzer IVD assay calibrators for measuring serum proteins. For professional use.
IVD Directive Category:	NOT Annex II and NOT self-test devices
Notified Body:	Not Applicable
Applicable Standards:	ISO 13485:2016, ISO 18113-2:2011, ISO 15223-1:2016, ISO 14971:2019
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Annex III. re Article 9, paragraph 5 of Directive 98/79/EC OR AS APPLICABLE

Signed: Satsuki Yoshimura Name: Satsuki Yoshimura

Position: Management Representative Date: September 9, 2020

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labeling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

KAMIYA BIOMEDICAL COMPANY

12779 Gateway Drive S., Tukwila, WA 98168 USA

TEL: (206) 575-8068
FAX: (206) 575 8094

ANNEX – Calibrator Product Listing/Schedule

Product Name / Description	Catalog Reference	GMDN Code
K-ASSAY® Urine Apha-1 Microglobulin Calibrator	KAI-067C	41258
K-ASSAY® Serum/Plasma Alpha-1 Microglobulin Calibrator	KAI-068C	41258
K-ASSAY® Apo AI/B Calibrator	KAI-008C	59060
K-ASSAY® Apo AII/CII/CIII Calibrator	KAI-041C	59060
K-ASSAY® Apo E Calibrator	KAI-025C	46070
K-ASSAY® ASO (WHO) Calibrator	KAI-079C	51744
K-ASSAY® Beta-2 Microglobulin Serum/Plasma Calibrator	KAI-281C	38215
K-ASSAY® Beta-2 Microglobulin Urine Calibrator	KAI-282C	38215
K-ASSAY® CRP Calibrator	KAI-012C	41838
K-ASSAY® CRP (3) Calibrator D	KAI-083C	41838
K-ASSAY® CRP (3) Calibrator E	KAI-084C	41838
K-ASSAY® CRP (3) Calibrator F	KAI-086C	41838
K-ASSAY® hsCRP Calibrator	KAI-161C	41838
K-ASSAY® Cystatin C Calibrator	KAI-099C	48174
K-ASSAY® D-Dimer Calibrator	KAI-091C	47348
K-ASSAY® High-Sensitive D-Dimer Calibrator	KAI-103C	47348
K-ASSAY® Factor XIII Calibrator	KAI-106C KAI-206C	56253
K-ASSAY® Plasma FDP Calibrator	KAI-112C	56109
K-ASSAY® Serum FDP Calibrator	KAI-321C	56109
K-ASSAY® Urine FDP Calibrator	KAI-326C	56109
K-ASSAY® Urine FDP Sample Diluent	KAI-109D	56109
K-ASSAY® Ferritin Calibrator	KAI-094C	41927
K-ASSAY® Fibrinogen Calibrator (L)	KAI-089C	55999
K-ASSAY® Fibrinogen Calibrator	KAI-136C	
K-ASSAY® H. Pylori Calibrator	KAI-241C	51023
K-ASSAY® Hemoglobin A1c Calibrator	KAI-098C KAI-311C	53315
K-ASSAY® Total IgE Calibrator	KAI-093C	53777
K-ASSAY® Insulin Calibrator	KAI-072C	42091
K-ASSAY® KL-6 Calibrator	KAI-251C	60555
K-ASSAY® Lp(a) Calibrator	KAI-018C	41417
K-ASSAY® Microalbumin Calibrator	KAI-020C	53477
K-ASSAY® Multi-Analyte Calibrator	KAI-016C	53593
K-ASSAY® Prealbumin Calibrator	KAI-054C	41387
K-ASSAY® RF Calibrator	KAI-032C	42230
K-ASSAY® RF Calibrator (Ver.2)	KAI-231C	42230
K-ASSAY® UIBC (Unsaturated Iron Binding Capacity) Calibrator	KAI-302C	58194
K-ASSAY® Vitamin C Calibrator	KT-75001 KT-75011	54461

End of Annex