LNE
Le progrès, une passion à partager

Certification Médical-Santé G MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 10462 rev. 6

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS
Zone Industrielle
61500 SEES FRANCE

pour les activités
for the activities

Conception, production, contrôle et commercialisation de réactifs de chimie clinique destinés aux laboratoires d'analyses de biologie.
Validation de la combinaison réactifs et automates.

Design, production, control and sales of clinical chemistry reagents intended to be used by clinical laboratories.
Validation of the combination reagents and instruments.

réalisées sur le(s) site(s) de
performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 - SEES - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **July 28th, 2017 (included)**
Valable jusqu'au */ Expiry date :* **July 27th, 2020 (included)**
Etabli le */ Issued on :* **July 27th, 2017**

Laboratoire national de métrologie et d'essais LNE

On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0038
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ_SPE-V0-04-2016

LNE N° 10462–6
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification

Renouvelle le certificat 10462-5

S.R.L. "GBG-MLD" SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 1 «METABOLITES DIVERS », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 1 "MISCELLANEOUS METABOLITES", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 1 "METABÓLICOS VARIOS ", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 18 Mai 2018

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 1 - METABOLITES DIVERS
GROUP 1 - MISCELLANEOUS METABOLITES
GRUPO 1 – METABÓLICOS VARIOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
ALBUMIN	ALBU-0600/0700/0250	DOS-CE-ALBU_R&Std	53597
ALBUMIN ENVOY	ALBU-0850		
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	DOS-CE-BILI 4+1	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250		53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600		53229/53233
CREATININE ENVOY	CRSL-0850	DOS-CE-CRSL	53250
CREATININE JAFFE	CRCO-0600/0700	DOS-CE-CRCO_R&Std	53251
CREATININE PAP SL	CRSL-0630/0250	DOS-CE-CRSL	53250
DIRECT BILIRUBIN ENVOY	BIDV-0850	DOS-CE-BIDV	53233
GLUCOSE ENVOY	GPSL-0850	DOS-CE-GPSL_R&Std	53301
GLUCOSE HK-SL	GHSL-0600/0250	DOS-CE-GHSL	
GLUCOSE PAP SL	GPSL-0495/0500/0700/ 0507/0707/0250/0455/0497	DOS-CE-GPSL_R&Std	
HEMOGLOBIN	HEMO-0400	DOS-CE-HEMO	32430
IRON TIBC	FECA-0050	DOS-CE-TIBC	53904
LACTATE	LACT-0100	DOS-CE-LACT	53342
MICROPROTEIN PLUS	PRTU-0600/0250	DOS-CE-PRTU_R&Std	53481
PHOSPHORUS	PHOS-0600/0230	DOS-CE-PHOS_R&Std	59123
PHOSPHORUS ENVOY	PHOS-0850		
TOTAL BILIRUBIN ENVOY	BITV-0850	DOS-CE-BITV	53229
TOTAL PROTEIN	PRTB-0600	DOS-CE-PRTB	53985
TOTAL PROTEIN ENVOY	PROB-0850	DOS-CE-PROB_R&Std	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250		
UREA ENVOY	URSL-0850	DOS-CE-URSL_R&Std	53587
UREA UV	URUV-0400	DOS-CE-URUV	
UREA UV SL	URSL-0400/0420/0500 0407/0427/0507/0250/0455	DOS-CE-URSL_R&Std	
URIC ACID	ACUR-0200/0400	DOS-CE-ACUR	53583
URIC ACID ENVOY	AUVD-0850	DOS-CE-AUVD	
URIC ACID MONO SL	AUML-0420/0500/0700/ 0427/0497/0507/0707/0250	DOS-CE-AUML_R&Std	
URIC ACID SL	AUSL-0250	DOS-CE-AUSL	

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 2 « ENZYMES », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 2, "ENZYMES", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 2 : "ENZIMAS", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 28 Juillet 2017

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 2 - ENZYMES
GROUP 2 – ENZYMES
GRUPO 2 – ENZIMAS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
ALP (DEA) SL	PASL-0400/0420/0230	DOS-CE-PASL	52928
ALP ENVOY	PIVD-0850	DOS-CE-PIVD	
ALT ENVOY	ALSL-0850	DOS-CE-ALSL 4+1	52923
ALT /GPT	ALAT-0200/0400	DOS-CE-ALAT	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	DOS-CE-ALSL 4+1	
AMYLASE ENVOY	AMSL-0850	DOS-CE-AMSL	52940
AMYLASE SL	AMSL-0390/0400/0230		
AST ENVOY	ASVD-0850	DOC-CE-ASVD	52954
AST/GOT	ASAT-0200/0400	DOS-CE-ASAT	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	DOC-CE-ASSL 4+1	
CHOLINESTERASE	CHES-0053	DOS-CE-CHES	52971
CK ENVOY	CKSL-0850	DOS-CE-CKSL	53003
CK-MB	CKMB-0030	DOS-CE-CKMB	52994
CK-MB ENVOY	CMSL-0850	DOS-CE-CMSL	
CK-MB SL	CMSL-0410/0430/0230		
CK NAC	CKNA-0030	DOS-CE-CKNA	53003
CK NAC SL	CKSL-0410/0430/0230	DOS-CE-CKSL	
GAMMA-GT SL PLUS	GISL-0400/0420/0500/0250	DOS-CE-GISL	53027
GGT ENVOY	GISL-0850		
LDH ENVOY	LLSL-0850	DOS-CE-LLSL	53072
LDH-L SL	LLSL-0400/0420/0230		
LDH-P	LDHP-0030	DOS-CE-LDHP	
LIPASE ENVOY	LPSL-0850	DOS-CE-LPSL	53108
LIPASE SL	LPSL-0230		

ELITech Clinical Systems SAS

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 3 «ELECTROLYTES/OLIGO-ELEMENTS», référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 3 "ELECTROLYTES/TRACE-ELEMENTS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 3 "ELECTROLITOS/OLIGO-ELEMENTOS ", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 29 juin 2018

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 3 – ELECTROLYTES / OLIGO-ELEMENTS
GROUP 3 – ELECTROLYTES / TRACE-ELEMENTS
GRUPO 3 – ELECTROLITOS / OLIGO-ELEMENTOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CALCIUM ARSENAZO	CALA-0600/0250	DOS-CE-CALA_R&Std	45789
CALCIUM ENVOY	CALA-0850		
CHLORIDE	CHLO-0600/0250	DOS-CE-CHLO_R&Std	60037
IRON CHROMAZUROL	FECA-0600	DOS-CE-FECA	54758
IRON ENVOY	FEFE-0850	DOS-CE-FEFE-R&Std	
IRON FERENE	FEFE-0230/0600		
IRON FERROZINE	FEFR-0600	DOS-CE-FEFR_R&Std	
MAGNESIUM CALMAGITE	MAGN-0600	DOS-CE-MAGN_R&Std	46795
MAGNESIUM ENVOY	MAGX-0850	DOS-CE-MAGX-R&Std	
MAGNESIUM XYLIDYL	MAGX-0230/0600		

VG

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 4 «LIPIDES », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 4 "LIPIDS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 4 "LÍPIDOS ", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 28 Juillet 2017

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. +33(0)2 33 81 21 00 - Fax +33(0)2 33 28 77 51

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 4 – LIPIDES
GROUP 4 – LIPIDS
GRUPO 4 – LÍPIDOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CHOLESTEROL	CHOL-0220/0420	DOS-CE-CHOL	53359
CHOLESTEROL ENVOY	CHSL-0850	DOS-CE-CHSL	
CHOLESTEROL SL	CHSL-0495/0500/0700/ 0507/0707/0250/0455/0497		
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	DOS-CE-HDLL	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	DOS-CE-LDLL	53395
HDL CHOLESTEROL	HDLC-0060	DOS-CE-HDLC	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	DOS-CE-HDLL	
LDL CHOLESTEROL ENVOY	LDLL-0850	DOS-CE-LDLL	53395
TRIGLYCERIDES	TRIG-0200/0400	DOS-CE-TRIG	53460
TRIGLYCERIDES ENVOY	TGML-0850	DOS-CE-TGMLN	
TRIGLYCERIDES MONO SL NEW	TGML-0425/0495/0515/ 0700/0427/0517/0707/0497		
TRIGLYCERIDES SL	TGML-0250/0455		

ELITech Clinical Systems SAS

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 5 «CONTRÔLES/ CALIBRANTS/ STANDARDS », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 5, "CONTROLS/ CALIBRATORS/ STANDARDS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 5 "CONTROLES/ CALIBRADORES/ ESTÁNDARES", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 28 Juillet 2017

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIREN 318 365 228 RCS ALENCON

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200	44698
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT	44693
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2	44700
ELICAL 2	CALI-0550	DOS-CE-CALI2	47868
ELITROL I	CONT-0060	DOS-CE-ELIT I	47869
ELITROL II	CONT-0160	DOS-CE-ELIT II	41818
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100	47869
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT	53482
ISE CONTROL II	ISCT-0047	DOS-CE-PRTU100	44702
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-TRIG200	53588
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-URUV50	44704
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-ACUR6	
URIC ACID Standard 6 mg/dL	ACUR-0055		

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

Organisme accrédité COFRAC N° 4-0023
Accredited body by COFRAC N° 4-0023

AB certification

CERTIFICAT
CERTIFICATE

N° A 3001

Nous certifions par la présente que le Système de Management de la Qualité de la société :
We hereby certify that the Quality Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy - France

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 9001 : 2015

Le domaine d'application du Système de Management de la Qualité est le suivant :
The scope of the Quality Management System is:

CONCEPTION, FABRICATION ET VENTE DE DISPOSITIFS MÉDICAUX DE DIAGNOSTIC IN VITRO. SUPPORT TECHNIQUE ET SERVICE D'ASSISTANCE.

DESIGN, MANUFACTURING AND SALE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES. TECHNICAL SUPPORT AND SUPPORT SERVICES.

Ce certificat demeurera en vigueur jusqu'à sa fin de validité à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management de la Qualité soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
This certificate is valid until its expiry date unless further notice, provided that the compliance and implementation of the Quality Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 24 décembre 2018
Signed in PARIS on the 24th of December 2018

Date de validité : 23 décembre 2021
Expiry date: 23rd of December 2021

"GBG-MLD" Nr.4

Georges ABI RACHED
Le Représentant d'AB Certification
AB Certification Representative

Le Représentant de l'Entreprise
The Company Representative

cofrac
CERTIFICATION DE SYSTÈMES DE MANAGEMENT
Accréditation N°4-0023
PORTÉE DISPONIBLE SUR www.cofrac.fr

Organisme accrédité COFRAC N° 4-0023
Accredited body by COFRAC N° 4-0023

125 DS 02 M16
ind 0 juin 17

AB certification

CERTIFICAT
CERTIFICATE

N°A 3001

Nous certifions par la présente que le Système de Management de la Qualité des Dispositifs Médicaux de la société :
We hereby certify that the Medical Devices Quality Management System of the company:

BIOLABO
LES HAUTES RIVES
02160 Maizy - France

est conforme aux exigences de la norme suivante :
is in compliance with the requirements of the following standard:

ISO 13485 : 2016

Le domaine d'application du Système de Management de la Qualité des Dispositifs Médicaux est le suivant :
The scope of the Medical Devices Quality Management System is as follows:

CONCEPTION, FABRICATION ET VENTE DE DISPOSITIFS MÉDICAUX DE DIAGNOSTIC IN VITRO. SUPPORT TECHNIQUE ET SERVICE D'ASSISTANCE.

DESIGN, MANUFACTURING AND SALE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES. TECHNICAL SUPPORT AND SUPPORT SERVICES

Ce certificat demeurera en vigueur pour une période de trois ans à moins d'avis contraire, à condition que la mise en place et la conformité du Système du Management de la Qualité des Dispositifs Médicaux soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.
This certificate is valid for a three-year period unless further notice, provided that the compliance and implementation of the Medical Devices Quality Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 24 décembre 2018
Signed in PARIS on the 24th of December 2018

Date de validité : 23 décembre 2021
Expiry date: 23rd of December 2021

Georges ABI RACHED
Le Représentant d'AB Certification
AB Certification Representative

Le Représentant de l'Entreprise
The Company Representative

cofrac
CERTIFICATION DE SYSTÈMES DE MANAGEMENT
Accréditation N°4-0023
PORTÉE DISPONIBLE SUR www.cofrac.fr

REPUBLIQUE FRANCAISE

CCI PARIS ILE-DE-FRANCE

Direction Générale Adjointe - Services aux Entreprises et Développement International
Direction des réseaux et partenariats internationaux
Service CLV

Certificat de Libre Vente pour l'exportation vers les pays non membres de l'Union Européenne

Free sale certificate for exportation to the non-EC Member States

dispositifs médicaux de diagnostic in vitro relevant de la directive n°98/79/CE
in vitro diagnostic medical devices covered by Directive 98/79/EC

PARTIE A COMPLETER PAR LE DEMANDEUR
Section to be completed by the applicant

Catégorie(s) du(des) dispositif(s) : : Réactifs et instruments de laboratoires pour la Biologie Médicale

Device(s) category: Reagents § Instruments for Medical Biology

Nombre de page en annexe : 5
Page in annex : 5

La désignation du(des) dispositif(s) apparait sur la déclaration(s) CE de conformité du fabricant ou du mandataire
The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative

Classification du(des) dispositif(s) :
Classification of the device(s) :

☐ **dispositif de l'annexe II liste A**
device of list A annex II

☐ **dispositif de l'annexe II liste B**
device of list B annex II

☐ **autotest hors annexe II**
device for self-testing not listed in annex II

☒ **autre dispositif (tous les dispositifs saufdispositifs de l'annexe II et autotests)**
other device (all devices except annex II and self-testing devices

Nom et adresse du fabricant ou du mandataire :
Name and address of the manufacturer or the authorized representative:
BIOLABO SAS / Mr Jean François CHARPENTIER, Les Hautes Rives 02160 MAIZY

Nom et adresse du site de production (facultatif):
Name and address of Production site (optional):
BIOLABO SAS, Les Hautes Rives 02160 MAIZY

Je soussigné Isabelle, Oget, Directrice Affaires Réglementairescertifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux de diagnostic in vitro figurant sur la(les) déclaration(s) CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°98/79/CE et répondent aux exigences essentielles de santé et de sécurité.
I the undersigned Isabelle, Oget, Director of Regulatory Affairs declare that the information above-mentioned is correct and the in vitro diagnostic medical devices on the EC declaration(s) of conformity are CE marked under my responsibility within the meaning of the European directive n°98/79/EC and fulfil the essential requirements of health and safety.

Date :30/08/2018

Signature :

BIOLABO S.A.S.
Les Hautes Rives
02160 MAIZY - FRANCE
Phone : +33 (0)3 23 25 [illegible]
Fax : +33 (0)3 23 25 62 [illegible]
Siret 317 598 832 00016
TVA : Fr 82 317 598 832

PARTIE RESERVEE A LA CCIR PARIS IDF
Section reserved for the administration

Les dispositifs médicaux de diagnostic in vitro marqués CE en conformité avec la directive 98/79/CE peuvent être mis sur le marché en France et dans les autres Etats membres de l'Union Européenne et parties à l'accord sur l'espace économique européen, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant des dispositifs concernés, d'une déclaration de conformité (autre dispositifs), accompagnée le cas échéant, des certificats nécessaires délivrés par un organisme notifié (dispositif de l'annexe II liste A et liste B, autotests hors annexe II).
Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

CCIR Paris IDF / DGA-SEDI
Service des CLV
9, rue Coquillière
75001 PARIS

Le Responsable du département
des Facilitations du Commerce Extérieur
CCIR Paris IDF

SOCIETATEA CU R.L. SRL 1003600117582 MD MOLDOVA MUN. CHIȘINĂU REPUBLICA MOLDOVA GBG-MLD

The in vitro medical devices CE marked in conformity with the directive 98/79/EC can be placed on the French market and in the other Member states of the European Union and part of the European Free Trade Association, and be exported in the non-EC Member States. This free sale certificate is valid until the maintenance, by the manufacturer of the concerned devices, of an CE declaration of conformity (other devices) together with when appropriate, the certificates delivered by a notified body (devices of list A and B, annex II, devices for self-testing not listed in annex II). This free sale certificate can only be used for exportation outside European Union.

BIOLABO - Désignation des Dispositifs / Devices Designation p1/5

REF	DESIGNATION FR	DESIGNATION GB
80351	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80001	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
87601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80501	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
LP80601	ACIDE URIQUE Méthode Uricase	URIC ACID Uricase Method
80002	ALBUMINE Méthode BCG	ALBUMIN BCG Method
99029	ALCOOL Ethanol	ALCOHOL Ethanol
99059	ALCOOL Ethanol	ALCOHOL Ethanol
80027	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80127	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80227	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
80327	ALT TGP (IFCC) Monoréactif	ALT GPT (IFCC) Single vial
LP80507	ALT TGP (IFCC)	ALT GPT (IFCC)
LP80607	ALT TGP (IFCC)	ALT GPT (IFCC)
92027	ALT TGP Méthode Colorimétrique	ALT GPT Colorimetric Method
99523	AMYLASE CNPG3	AMYLASE CNPG3
99123	AMYLASE CNPG3	AMYLASE CNPG3
99223	AMYLASE CNPG3	AMYLASE CNPG3
LP99553	AMYLASE CNPG3	AMYLASE CNPG3
80023	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
80123	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
80223	AMYLASE Méthode E-PNPG7	AMYLASE E-PNPG7 Method
99261	AMMONIAC Méthode Enzymatique	AMMONIA Enzymatic Method
80025	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80125	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80225	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
80325	AST TGO (IFCC) Monoréactif	AST GOT (IFCC) Single vial
LP80505	AST TGO (IFCC)	AST GOT (IFCC)
LP80605	AST TGO (IFCC)	AST GOT (IFCC)
92025	AST TGO Méthode Colorimétrique	AST GOT Colorimetric Method
92026	Solution Soude 0,4 N	NaOH Solution 0.4 N
99832	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
99852	BICARBONATE Méthode Enzymatique	BICARBONATE Enzymatic Method
80403	BILIRUBINE TOTALE ET DIRECTE Méthode Acide Sulfanilique	TOTAL AND DIRECT BILIRUBIN Sulfanilic Acid Method
80443	BILIRUBINE TOTALE Méthode Acide Sulfanilique	TOTAL BILIRUBIN Sulfanilic Acid Method
80553	BILIRUBINE DIRECTE Méthode Acide Sulfanilique	DIRECT BILIRUBIN Sulfanilic Acid Method
97443	BILIRUBINE TOTALE Méthode DCA	TOTAL BILIRUBIN DCA Method
97553	BILIRUBINE DIRECTE Méthode DCA	DIRECT BILIRUBIN DCA Method
90004	CALCIUM Méthode Arsenazo III	CALCIUM Arsenazo III Method
80004	CALCIUM Méthode CPC	CALCIUM CPC Method
80005	CHLORURES Méthode Colorimétrique	CHLORIDE Colorimetric Method
80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
LP80106	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
87656	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
88656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
99656	CHOLESTEROL Non estérifié CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP
87356	CHOLESTEROL CHOD-PAP	CHOLESTEROL CHOD-PAP
90206	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90406	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
90426	CHOLESTEROL-HDL Méthode Directe	HDL-CHOLESTEROL Direct Method
86536	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
85516	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Precipitant
90416	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
90816	CHOLESTEROL-LDL Méthode Directe	LDL-CHOLESTEROL Direct Method
82526	CHOLINESTERASE Butyrylthiocholine	CHOLINESTERASE Butyrylthiocholine
97217	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method
97317	Isoenzyme CK-MB Méthode d'immunoinhibition	CK-MB Isoenzyme Immunoinhibition Method

BIOLABO - Désignation des Dispositifs / Devices Designation p2/5

REF	DESIGNATION FR	DESIGNATION GB
92207	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
92307	CK-NAC IFCC Monoréactif	CK-NAC IFCC Single Vial
80107	CREATININE Méthode cinétique	CREATININE Kinetic method
80008	FER (SFBC) Bathophénanthroline	IRON (SFBC) Bathophenanthrolin
92108	FER Méthode directe (Férène)	IRON Direct Method (Ferene)
92306	C.T.F. Capacité Totale de Fixation du Fer	T.I.B.C. Total Iron Binding Capacity
97408	C.L.F. Capacité Latente de Fixation du Fer	U.I.B.C Unsaturated Iron Binding Capacity
97089	G6-PDH Méthode cinétique U.V.	G6-PDH U.V. Kinetic Method
97099	G6-PDH lyophilisée Méthode cinétique U.V.	Lyophilised G6-PDH U.V. Kinetic Method
81110	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81210	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
81310	GAMMA GT GPNA carboxylé	GAMMA GT carboxy GPNA
80009	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87109	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
87409	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
16GL8	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP80209	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
LP87809	GLUCOSE GOD-PAP	GLUCOSE GOD-PAP
3502200	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
82250	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
92011	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92111	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
92511	L.D.H. (LDH-P) Méthode SFBC modifiée	L.D.H. (LDH-P) SFBC Modified Method
99881	LIPASE Méthode cinétique	LIPASE Kinetic Method
99891	LIPASE Méthode cinétique	LIPASE Kinetic Method
87212	MAGNESIUM Calmagite	MAGNESIUM Calmagite
98212	MAGNESIUM CALMAGITE Haute Stabilité - Haute Linéarité	MAGNESIUM CALMAGITE High Stability - High Linearity
92214	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE (DEA)
92314	PHOSPHATASE ALCALINE (DEA)	ALKALINE PHOSPHATASE (DEA)
82560	PHOSPHATASE ACIDE Méthode Cinétique	ACID PHOSPHATASE Kinetic Method
3300060	PHOSPHATASE ACIDE Méthode Point Final (PNPP)	ACID PHOSPHATASE End Point Method (PNPP)
99105	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
99110	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDS Colorimetric enzymatic Method
80015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHORUS U.V. Method
80016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
LP87016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
97016	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogallol Red Method
80019	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
87319	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80519	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
LP80619	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
80221	UREE Méthode colorimétrique	UREA Colorimetric Method
80321	UREE Méthode colorimétrique	UREA Colorimetric Method
92032	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
92132	UREE U.V. Méthode Cinétique	UREA U.V. Kinetic Method
99032	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
99132	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99532	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
LP99632	UREE U.V. Méthode Cinétique Haute Linéarité	UREA U.V. High Linearity Kinetic Method
92315	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
92330	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method

BIOLABO - Désignation des Dispositifs / Devices Designation p3/5

REF	DESIGNATION FR	DESIGNATION GB
95010	BIOLABO EXATROL-N Taux 1	BIOLABO EXATROL-N Level 1
95011	BIOLABO EXATROL-P Taux 2	BIOLABO EXATROL-P Level 2
95015	BIOLABO MULTICALIBRATOR Calibrateur Multiparamétrique	BIOLABO MULTICALIBRATOR Multiparametric calibrator
95020	BIOLABO EEQ Evaluation externe de la qualité	BIOLABO EQA External Quality Assessment
95403	BIOLABO CONTROLE PEDIATRIQUE	BIOLABO PAEDIATRIC CONTROL
95406	CALIBRATEUR CHOLESTEROL-HDL	HDL-CHOLESTEROL CALIBRATOR
95805	CALIBRATEUR CHOLESTEROL-LDL	LDL-CHOLESTEROL CALIBRATOR
95506	CALIBRATEUR HDL LDL CK-MB	HDL LDL CK-MB CALIBRATOR
95516	Sérum de contrôle HDL LDL CK-MB Lipides Taux 1	Control serum HDL LDL CK-MB Lipids Level 1
95526	Sérum de contrôle HDL LDL CK-MB Lipides Taux 2	Control serum HDL LDL CK-MB Lipids Level 2
95801	Calibrant LIPASE	LIPASE Calibrator
95013	Contrôle Normal AMMONIAC ALCOOL BICARBONATE	Normal Control AMMONIA ALCOHOL BICARBONATE
95023	Contrôle Pathologique AMMONIAC ALCOOL BICARBONATE	Pathological Control AMMONIA ALCOHOL BICARBONATE
95089	G6-PDH Contrôle normal (hémolysat humain lyophilisé)	G6-PDH Normal control (Lyophilised human hemolysed blood)
95289	G6-PDH Contrôle Déficient (hémolysat humain lyophilisé)	G6-PDH Deficient control (Lyophilised human hemolysed blood)
95012	Contrôle urinaire Taux 1 et Taux 2	Urinary Control Level 1 and Level 2
95315	KIT CALCULS URINAIRES Contrôles Positifs et Négatifs	STONE ANALYSIS SET Positive and Negative Controls
13880	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13885	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13881	BIO-TP Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13702	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13704	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13712	BIO-TP LI (Low ISI) Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13883	TAMPON OWREN KOLLER	OWREN KOLLER BUFFER
13560	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13570	BIO-CK TCA Kaolin	BIO-CK APTT Kaolin
13660	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13670	BIO-SIL TCA Silice	BIO-SIL APTT Silica
13565	CHLORURE DE CALCIUM 0,025M	CALCIUM CHLORIDE 0.025M
13450	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13451	BIO-FIBRI Dosage Chronométrique du Fibrinogène	BIO-FIBRI Chronometric determination of Fibrinogen
13980	BIO-TT Temps de Thrombine	BIO-TT Thrombin Time
13965	TP-CALSET Set de Plasmas de Référence	TP-CALSET Standard Set
13970	BIO-CAL Plasma de référence	BIO-CAL Reference Plasma
13961	PLASMA CONTRÔLE Taux 1	CONTROL PLASMA Level 1
13962	PLASMA CONTRÔLE Taux 2	CONTROL PLASMA Level 2
13963	PLASMA CONTRÔLE Taux 3	CONTROL PLASMA Level 3
13210	D-DIMER Test Immunoturbidimétrique	D-DIMER Turbidimetric Immunoassay
13211	D-DIMER Control 1	D-DIMER Control 1
13212	D-DIMER Control 2	D-DIMER Control 2
13302	FACTOR II Plasma Déficient	FACTOR II Deficient plasma
13305	FACTOR V Plasma Déficient	FACTOR V Deficient plasma
13307	FACTOR VII Plasma Déficient	FACTOR VII Deficient plasma

BIOLABO - Désignation des Dispositifs / Devices Designation p4/5

REF	DESIGNATION FR	DESIGNATION GB
13308	FACTOR VIII Plasma Déficient	FACTOR VIII Deficient plasma
13309	FACTOR IX Plasma Déficient	FACTOR IX Deficient plasma
13310	FACTOR X Plasma Déficient	FACTOR X Deficient plasma
13311	FACTOR XI Plasma Déficient	FACTOR XI Deficient plasma
13312	FACTOR XII Plasma Déficient	FACTOR XII Deficient plasma
13971	COATROL 1 Taux 1	COATROL 1 Level 1
13972	COATROL 2 Taux 2	COATROL 2 Level 2
9905TH	S. Typhi H (d,H)	S. Typhi H (d,H)
9905TO	S. Typhi O (9,12-O)	S. Typhi O (9,12-O)
9905AH	S. Paratyphi AH (a-H)	S. Paratyphi AH (a-H)
9905AO	S. Paratyphi AO (1,2,12-O)	S. Paratyphi AO (1,2,12-O)
9905BH	S. Paratyphi BH (b-H)	S. Paratyphi BH (b-H)
9905BO	S. Paratyphi BO (1,4,5-O)	S. Paratyphi BO (1,4,5-O)
9905CH	S. Paratyphi CH (c-H)	S. Paratyphi CH (c-H)
9905CO	S. Paratyphi CO (6,7-O)	S. Paratyphi CO (6,7-O)
9905BA	Brucella abortus	Brucella Abortus
9905PK	Proteus OXK	Proteus OXK
9905P19	Proteus OX19	Proteus OX19
9905P2	Proteus OX2	Proteus OX2
9905BM	Brucella Melitensis	Brucella Melitensis
9905RB	Rose Bengal (B. Abortus)	Rose Bengal (B. Abortus)
9901PC	Contrôle Positif Polyvalent	Positive Polyvalent Control
9901NC	Contrôle Négatif Polyvalent	Negative Polyvalent Control
99054	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
99056	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
99058	ANTIGENES FEBRILES Pour Tests de Widal Félix	STAINED FEBRILE ANTIGENS For Widal Felix Tests
081050	ASLO-LATEX	ASLO-LATEX
097100	CRP-LATEX	CRP-LATEX
096100	FR-LATEX	FR-LATEX
3800100	RPR-CHARBON	RPR-CHARBON
3800150	RPR-CHARBON	RPR-CHARBON
4500100	TPHA	TPHA
4500200	TPHA	TPHA
085100	HCG-LATEX	HCG-LATEX
RF050E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF520E	Facteurs Rhumatoides (FR) Test Immunoturbidimétrique	RHEUMATOID FACTOR (RF) Turbidimetric Immunoassay
RF CALSET51	BIOLABO FR Kit de Calibration	BIOLABO RF Standard Set
RF CALSH1	BIOLABO FR Calibrant Super Haut	BIOLABO RF Standard Super High
RF CONT1	BIOLABO FR Contrôle	BIOLABO RF Control
RF CONT5	BIOLABO FR Contrôle	BIOLABO RF Control
CRP050E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP620E	CRP Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP CALSET51	BIOLABO CRP Kit de Calibration	BIOLABO CRP Standard Set
CRP CALSH1	BIOLABO CRP Calibrant Super Haut	BIOLABO CRP Standard Super High
CRP CONTL1	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTL5	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP CONTH1	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
CRP CONTH5	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
ASLO050E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO620E	ASLO Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO CALH1	BIOLABO ASLO Calibrant Haut	BIOLABO ASLO Standard High
ASLO CALSH1	BIOLABO ASLO Calibrant Super Haut	BIOLABO ASLO Standard Super High

BIOLABO - Désignation des Dispositifs / Devices Designation p5/5

REF	DESIGNATION FR	DESIGNATION GB
ASLO CALSET41	BIOLABO ASLO Kit de Calibration	BIOLABO ASLO Standard Set
ASLO CONT1	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
ASLO CONT5	BIOLABO ASLO Contrôle	BIOLABO ASLO Control
APOA1620E	APOLIPOPROTEINE A1 Test Immunoturbidimétrique	APOLIPOPROTEINE A1 Turbidimetric Immunoassay
APOB620E	APOLIPOPROTEINE B Test Immunoturbidimétrique	APOLIPOPROTEINE B Turbidimetric Immunoassay
APOA1050E	APOLIPOPROTEINE A1 Test Immunoturbidimétrique	APOLIPOPROTEINE A1 Turbidimetric Immunoassay
APOB050E	APOLIPOPROTEINE B Test Immunoturbidimétrique	APOLIPOPROTEINE B Turbidimetric Immunoassay
A1B CALH1	BIOLABO A1B Calibrant Haut	BIOLABO A1B Standard High
A1B CONT1	BIOLABO A1B Contrôle	BIOLABO A1B Control
23010	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23011	MICROALBUMINE Test Immunoturbidimétrique	MICROALBUMIN Turbidimetric Immunoassay
23012	MICROALBUMINE Calibrant Super Haut	MICROALBUMIN Standard Super High
23013	MICROALBUMINE Kit de calibration	MICROALBUMIN Standard Set
23014	MICROALBUMINE Contrôle	MICROALBUMIN Control
22050	HbA1c ENZYM	HbA1c ENZYM
22052	HbA1c ENZYM Kit de calibration	HbA1c ENZYM Standard Set
22010	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22011	HbA1c Test Immunoturbidimétrique	HbA1c Turbidimetric Immunoassay
22012	HbA1c Kit de calibration	HbA1c Standard Set
22013	HbA1c Kit de contrôle	HbA1c Control Set
KENZA MAX	KENZA MAX BioChemisTry PHOTOMETRE	KENZA MAX BioChemisTry PHOTOMETER
KENZA 120TX	KENZA 120TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 120TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240TX	KENZA 240TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 240TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240ISE	KENZA 240ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE avec module ISE	KENZA 240ISE - AUTOMATIC BIOCHEMISTRY ANALYSER with ISE Module
KENZA 450TX	KENZA 450TX	KENZA 450TX
KENZA 450ISE	KENZA 450ISE	KENZA 450ISE
BIOSOLEA 2	BIO SOLEA 2 - COAGULOMETRE 2 CANAUX	BIO SOLEA 2 - COAGULOMETER 2 CHANNELS
BIOSOLEA 4	BIO SOLEA 4 - COAGULOMETRE 4 CANAUX	BIO SOLEA 4 - COAGULOMETER 4 CHANNELS
SOLEA 100	SOLEA 100 - ANALYSEUR AUTOMATIQUE D'HEMOSTASE	SOLEA 100 - FULL AUTOMATED COAGULATION ANALYSER
SCUP120	Serum Cup K120TX	Serum Cup K120TX
CO0080	SERUM CUPS	SERUM CUPS
CO4015	Extra Cleaning	Extra Cleaning
CO4020	Ipo Cleaning	Ipo Cleaning
CO0058	SERUM CUPS K450	SERUM CUPS K450
K450CS	Cleaning Solution K450	Cleaning Solution K450
RP240ISE	Pack Réactifs - ISE	Reagent Pack - ISE
G2058/A	Cleaning Solution - ISE	Cleaning Solution - ISE
5202	Electrode K - ISE	Electrode K - ISE
5205	Electrode Li - ISE	Electrode Li - ISE
5207	Electrode Cl - ISE	Electrode Cl - ISE
5201	Electrode Na - ISE	Electrode Na - ISE
5204	Electrode de référence	Reference Electrode
S100CS	CLEANING SOLUTION SOLEA 100	CLEANING SOLUTION SOLEA 100

СИСТЕМА СЕРТИФИКАЦИИ
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«СМК СТАНДАРТ»
Рег. № РОСС RU.31060.04ЖЖЮ0

Орган по сертификации:
РЕГ № SMK STANDART.RU.0005
Общество с ограниченной ответственностью
«МЕЖДУНАРОДНЫЙ ЦЕНТР СЕРТИФИКАЦИИ»
Адрес: 190020, г. Санкт-Петербург, наб. Обводного канала, д. 138, корпус 1, офис 421
тел +7 (812) 438-76-71 standart@iso-smk.ru
подлинность сертификата проверяйте в реестре на сайте http://www.iso-smk.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ ST.RU.0001.M0013380

выдан

Обществу с ограниченной ответственностью «Агат-Мед»
Адрес: 105173, г. Москва, ул. Главная, д.6, кв.12
ИНН 7719187311 ОГРН 1037739078970

Дата выдачи: 26.01.2018 г. Срок действия до: 26.01.2021 г.

Настоящий сертификат удостоверяет:
Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования применительно к работам согласно приложению №1к настоящему сертификату
(приложение является неотъемлемой частью сертификата)

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2011 (EN ISO 13485:2003)

Руководитель органа
_____ Копцев В. В.

Эксперт
_____ Гундарева О. В.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" Nr.4 IDNO 1003600117628 REPUBLICA MOLDOVA, MUK

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМ СТАНДАРТОМ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «СМК СТАНДАРТ» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

СИСТЕМА СЕРТИФИКАЦИИ
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
ПРИЛОЖЕНИЕ №1
к сертификату соответствия № ST.RU.0001.M0013380
Область сертификации системы менеджмента качества:

Разработка, производство и продажа медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов.

Руководитель органа _____ Концев В. В.

Эксперт _____ Гундарева О. В.

ООО "АГАТ-МЕД"
105173, Москва, ул. Главная 6-12
многоканальный т/ф. 777-41-92
факс/авт. (495)741-25-19;
т/ф. (499)780-97-48/84.
E-mail: agat@agat.ru, http://www.agat.ru

ПАСПОРТ

Набор реагентов для определения гемоглобина в крови гемиглобинцианидным методом
«Гемоглобин-АГАТ»
(600 опр. х 5 мл)

Серия **17/960918** Дата выпуска **09.2018** Годен до **10.2020**
Количество наборов в серии **50000**

Наименование показателя	Характеристика и норма по ТУ 9398-280-11498242-00	Результаты анализа
1. Внешний вид		
1.1.Трансформирующий реагент	Порошок желто-оранжевого цвета или смесь белых и оранжевых кристаллов	Смесь белых и оранженых кристаллов
1.2 Ацетонциангидрин	Бесцветная прозрачная жидкость	Бесцветная прозрачная жидкость
1.3 Калибровочный раствор гемоглобина	Прозрачная жидкость от темно-красного до темно-коричневого цвета	Прозрачная жидкость темно-красного цвета
2. Технические характеристики		
2.1 Тест на соответствие калибратора контрольному лабораторному раствору гемоглобина 120 г/л, отклонение в %, не более	2	Соответствует
2.2 Чувствительность, г/л, не более	10	Соответствует
3. Показатели правильности определения		
3.1 Тест на "линейность" в диапазоне концентраций от 20 до 200 г/л, отклонение в %, не более	2	Соответствует
3.2 Тест на "открытие", отклонение в %, не более	2	Соответствует
3.3 Коэффициент вариации результатов определения, %, не более	2	Соответствует
3.4 Допустимый разброс результатов при параллельных определениях одной пробы разными наборами одной серии, %, не более	2	Соответствует
3.5 Время выхода оптической плотности на устойчивые показатели после добавления анализируемой пробы,мин, не более	20	Соответствует

Заключение ОКК ООО «Агат-Мед»:
Серия **17/960918** соответствует требованиям ТУ 9398-280-11498242-00

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«1.» сентября 2018 г.

"Агат-Мед"

ООО "АГАТ-МЕД"
105173, Москва, ул. Главная 6-12
многоканальный т/ф. 777-41-92
факс/авт. 741-25-19;
т/ф. (499)780-97-48/84.
E-mail: agat@agat.ru, http://www.agat.ru

ПАСПОРТ

Раствор гемоглобина калибровочный, 120 г/л, 1 фл. х 2 мл
«АГАТ-Калибратор Гемоглобин 120».

Серия **11404/301118** Дата выпуска **11.2018** Годен до **12.2020**
Количество наборов в серии **5000**

Наименование показателя	Характеристика и норма по ТУ 9398-262-11498242-2003	Результаты анализа
1. Внешний вид	Жидкость от темно-красного до темно-коричневого цвета	Жидкость соответствует темно-красного цвета
2. Допустимые отклонения концентрации гемоглобина от аттестованного значения, % не более	2	Соответствует
3. Коэффициент вариации результатов определения, % не более	2	Соответствует
4. Допустимый разброс результатов при параллельных определениях гемоглобина в разных флаконах одной серии, % не более	2	Соответствует

Заключение ОКК ООО «Агат-Мед»:
Набор серии **11404/301118** требованиям ТУ 9398-262-11498242-2003 соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.

«28» ноября 2018г.

МП

Копия для Электрогорск Соловьева Т.В. к документу РасходнаяБН № 561242 от 28.11.18 к товару поз. 2

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 28 октября 2013 года № ФСР 2009/04472

На медицинское изделие
Набор реактивов для тимоловой пробы "Тимоловая проба-Агат"

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Агат-Мед"
(ООО "Агат-Мед"), Россия,
105173, г. Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Производитель
Общество с ограниченной ответственностью "Агат-Мед"
(ООО "Агат-Мед"), Россия,
105173, г. Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Место производства медицинского изделия
105173, г. Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Номер регистрационного досье № РД-2080/39533 от 23.10.2013

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия **2а**

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 28 октября 2013 года № 6179-Пр/13
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения М.А. Мурашко

0005064

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 25 ноября 2011 года № ФСР 2011/12395

На медицинское изделие
Набор реагентов для определения гемоглобина в крови гемиглобинцианидным методом «Гемоглобин-Агат» по ТУ 9398-280-11498242-00

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Агат-Мед" (ООО "Агат-Мед"), Россия, 105173, Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Производитель
Общество с ограниченной ответственностью "Агат-Мед" (ООО "Агат-Мед"), Россия, 105173, Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Место производства медицинского изделия
105173, Москва, поселок Восточный, ул. Главная, д. 6, кв. 12

Номер регистрационного досье № 41794 от 19.10.2011

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 25 ноября 2011 года № 7750-Пр/11

S.R.L. "GBG-MLD" IDNO 1003600117582 REPUBLICA MOLDOVA, MUN.

и приказом от 10 декабря 2013 года № 7123-Пр/13 о замене
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения М.А. Мурашко

0005897

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 25 ноября 2011 года № ФСР 2011/12395

На медицинское изделие

Набор реагентов для определения гемоглобина в крови гемиглобинцианидным методом «Гемоглобин-Агат» по ТУ 9398-280-11498242-00

1. Трансформирующий реагент (сухая смесь 200 мг) - 3 упаковки.
2. Ацетонцианангидрин - 3 ампулы (по 0,5 мл).
3. Калибровочный раствор гемоглобина с концентрацией 120 г/л - 1 флакон (2 мл).

Приказом от 10 декабря 2013 года № 7123-Пр/13 о замене допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы по надзору в сфере здравоохранения М.А. Мурашко

0005004

BUREAU VERITAS
Certification

Certificate

Awarded to

Avantor Performance Materials Poland S.A.

ul. Sowińskiego 11, 44-101 GLIWICE
POLAND

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

STANDARD

ISO 9001:2015

SCOPE OF SUPPLY

SALES OF CHEMICAL SERVICES AND CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS, HIGH PURITY SOLVENTS, CHEMICAL SERVICES.

PRODUCTION AND TESTING OF CHEMICAL PRODUCTS INCLUDING FINE CHEMICALS, ENNOBLED CHEMICALS AND HIGH PURITY SOLVENTS.

Certification Cycle Start Date: **15 September 2018**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: **14 September 2021**

To check this certificate validity please call: +48 22 549 04 00
Further clarification regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

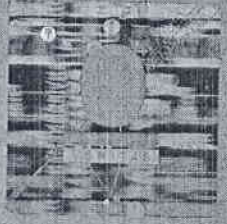
Issue Date: 29 June 2018

Certificate Number: **PL008875/P**

Piotr Popławski
Local Technical Manager

MIX
Paper from responsible sources
FSC® C074440

PCA
Polskie Centrum Akredytacji
CERTYFIKACJA SYSTEMÓW ZARZĄDZANIA
AC 081
QMS



avantor™

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459.9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832.9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823.1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431.1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN-free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ R20	3853.1000	1 L
CyMet™ RX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
CyMet™ NR V	3486.1000PE	1 L
CyMet™ Ruby CN Free	3485.1000PE	1 L
CyMet™ ST 1600/2000 CN free	2988.5000PC	5 L
LeucoLyse	3759.5000	5 L
LeucoLyse Ruby	3475.5000PC	5 L
	2989.5000PC	5 L
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768.1000	1 L micros
ProClean™ Abacus	3432.5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862.5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Cervix Spray Fixative	3869.1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933.1000	1 L
	3933.5000PC	5 L
	3933.9010	10 L
	3933.9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856.1000	1 L
	3856.2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870.1000	1 L
	3870.2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873.1000	1 L
	3873.2500	2.5 L
May-Grünwald	3855.1000	1 L
	3855.2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555.2500PE	2.5 L
Papanicolaou 3B	3556.1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921.0500	500 ml
	3921.0600	6 x 100 ml
	3921.9025ST	25 L
Mounting medium High	3882.0500	500 ml
Mounting medium Low	3883.0500	500 ml
PBS	3059	20 L
	3059.9010PC	10 L

Abbott

Declaration of Conformity

Certificate Identification: SC-09H73

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H73-01	55865	CELL-DYN 22 Plus Calibrator	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Streck, Inc. 7002 S. 109th Street La Vista, NE 68128 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	A W Evans	Signature:	
Full Name:	Alfred Evans	Full Name	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	May 8, 2019	Date of Approval:	May 8, 2019
Date Issued:	MAY 09 2019	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1 April 15, 2016	Effective (Date or Lot Number):	MAY 09 2019

Abbott

Declaration of Conformity

Certificate Identification: SC-09H62

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H62-01	58237	CELL-DYN Emerald 22 DILUENT	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRI S V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H60

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H60-01	58236	CELL-DYN Emerald 22 Easy Cleaner	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Kevin Richardson	Signature	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H61

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H61-01	61165	CELL-DYN Emerald 22 LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

SOCIETATEA PE RASPUNDERE LIMITATA "GBG-MLD" S.R.L. IDNO 1003600017582 REPUBLICA MOLDOVA, MUN. CHISINAU

Abbott

Declaration of Conformity

Certificate Identification: SC-09H72

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H72-01	55866	CELL-DYN 22 Plus Control, Full Pack	Self-declared
09H72-02	55866	CELL-DYN 22 Plus Control, Half Pack	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Streck, Inc. 7002 S. 109th Street La Vista, NE 68128 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Alfred Evans	Full Name:	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	May 9, 2019	Date of Approval:	May 9, 2019
Date Issued:	MAY 09 2019	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1 April 15, 2016	Effective (Date or Lot Number):	MAY 09 2019

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The Design, Development, Manufacture, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM Accrédité CCN

Calin Moldovean
President
Intertek Testing Services NA Ltd.
1829, 32nd avenue, Lachine, QC, H8T 3J1, Canada

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Products For Health Care

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH
EasyElectrolyte and accessories per attachment	EasyElectrolyte Na/K/Cl, Na/K/Li
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Molenstraat 15
NL-2513 BH The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

Place and Date: Bedford, Massachusetts, USA, March 1, 2012

Signature:

Photios Makris

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Refrence Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenace Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14
Expiry Date: 2021-04-13

...making excellence a habit.

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14
Expiry Date: 2021-04-13

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Declaration of Conformity

HL-7- 0163 DC DOI 2014/05 (8)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5265	Thromboplastin LI	55983
5265H	Thromboplastin LI	55983
5267	Thromboplastin LI	55983
5269	Thromboplastin LI	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 07 May 2014

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0511 DC DOI 2013/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

4426

File Number	A12241	Cycle Start Date	June 26, 2018
Certificate	1458.180626	Effective Date	June 26, 2018
Initial Issue	June 26, 2018	Expiry Date	May 22, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096
USA

00-MB-S0043 Issue 15.0

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

File No A12241;
ISO 13485:2003; ISO 9001:2008

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

File No A12241;
ISO 13485:2003; ISO 9001:2008

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 65

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

4426
File No A12241;
ISO 13485:2003; ISO 9001:2008

Registered office as above. Registered in England No. 04540707. VAT No. 800 3655 66

NovaTec Immundiagnostica GmbH

Product List – CE Marked

Certified by

ISO 13485:2012

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2018-02

19022018-Dö

NovaTec Immundiagnostica GmbH

NovaLisa® Prod. No.	Virology Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG

19022018-Dö

RUBM0400	Rubella Virus IgM µ-capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Bacteriology

Prod. No.	Name
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM
MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM

NovaTec Immundiagnostica GmbH

TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa ® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
GIA0160S	Giardia lamblia antigen
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa ® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

19022018-Dö

NovaTec Immundiagnostica GmbH

NovaLisa ® Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
TSH1030	TSH

NovaLine

Prod. No.	Name
TRYG2570	Chagas IgG **LineBlot**

Hormones

STEROID HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV007	Free Estriol
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estriol
DNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV22	17 beta-Estradiol Saliva

NovaTec Immundiagnostica GmbH

DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estriol Saliva
DSNOV27	Androstenedione Saliva

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Fee T3
DNOV052	FreeT4
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3

19022018-D6

DNOV063	CA 19-9

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa ® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovaLisa ® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HSV1G0500	Herpes simples Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
TREG0470	Treponema pallidum
ZVG0790	Zika Virus IgG capture

ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa ® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaTec Immundiagnostica GmbH

Antigen Assays

Prod. No.	Name
GIA0160S	Giardia lamblia antigen

NovaLisa ® IgM µ-capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM µ-capture
DVM0640	Dengue Virus IgM µ-capture
RUBM0400	Rubella Virus IgM µ-capture
TOXM0460	Toxoplasma gondii IgM µ-capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa ® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG

NovaTec Immundiagnostica GmbH

BORM0040	Borrelia burgdorferi IgM

Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату

применительно к областям

проектирование и разработка, производство и реализация медицинских изделий in-vitro диагностики (ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала, что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества – Регулирующие системные требования

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи	2018-07-13
Срок действия до	2020-07-03
Регистрационный №	D1213100017
Отчет №	P18-00489-117996
Штутгарт, Германия	2018-07-13

Руководитель сертификационного органа

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegsstraße 6
D-70191 Stuttgart, Germany
Phone: +49 (0)711 253927-0
Fax: +49 (0)711 253927-10
Internet: http://www.mdc-ce.de

Приложение к Сертификату

№ D1213100017 от 2018-07-13 Стр. 1 из 1

Месторасположение	Область действия
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

Руководитель сертификационного органа

medical device certification mdc

mdc medical device certification GmbH
Kriegsstraße 6
D-70191 Stuttgart, Germany
Phone: +49 (0)711 253927-0
Fax: +49 (0)711 253927-10
Internet: http://www.mdc-ce.de

Quality System Approval Certificate
In Vitro Diagnostic Medical Devices Directive 98/79/EC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (In Vitro Diagnostics Medical Devices) Regulations (S.I. No. 304 of 2001)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Monobind Inc.

100 North Pointe Drive
Lake Forest
CA 92630
USA

For the Product Family

Total and Free Prostate Specific Antigen (PSA and Free PSA) IVD, kit, chemiluminescent immunoassay (CLIA) and enzyme immunoassay (ELISA) and control

GMDN Code: 54664, 54669

On the basis of examination under the requirements of Annex IV, Section 3 of Directive 98/79/EC,
The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product is hereby authorized.

Registration Number:	**304.1006**
Original Registration:	**28 October 2011**
Last Amended on:	**10 July 2018**
Remains valid until:	**27 October 2022**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

The National Standards Authority of Ireland certifies that:

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: Oct 29, 2017
Expiry Date: Oct 28, 2020

NSAI

Annex to Certificate Number: MD19.4585

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585
Manufacture, Design	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585/A

Verified by:
Operations Manager

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

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 Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13, NL tel: +31 (0)6 – 516.536.26)

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

Immunoassay products;
ELISA,
CLIA,
Control,
Instruments (see appendix)

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

Document No.	Title	Edition / Date of issue
L 331; 98/79/EC	In-Vitro-Diagnostic Directive	1998-10-27

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

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Lake Forest, USA;2011-09-27 ---------- AShatola ----------

Tony Shatola; QA Director, Monobind Inc.

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Maarn, NL; 2011-09-27 ----------

Olga Terlinck; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of authorized representative)*

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
Thyroid								
T3 – Triidothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
fT3 – Free Triidothyronine	1325-300	1375-300			12.04.01.01.00	Low		2005-11-11
T4 – Thyroxine	225-300	275-300			12.04.01.07.00	Low		2005-11-11
fT4 – Free Thyroxine	1225-300	1275-300			12.04.01.02.00	Low		2005-11-11
TSH – Thyrotropin	325-300	375-300			12.04.01.11.00	Low		2005-11-11
Rapid TSH – Rapid Thyrotropin	6025-300	6075-300			12.04.01.11.00	Low		2010-06-29
T3U – Triidothyronine Uptake	525-300	575-300			12.04.01.06.00	Low		2005-11-11
TBG – Thyroxine-Binding Globulin	3525-300	3575-300			12.04.01.09.00	Low		2005-11-11
Tg – Thyroglobulin	2225-300	2275-300			12.04.01.08.00	Low		2005-11-11
T3, T4 & TSH – Triidothyronine, Thyroxine & Thyrotropin Combo (VAST)	8025-300	8075-300			12.04.01.01.00	Low		2005-11-11
T3 – Triidothyronine (SBS)	8125-300	8175-300			12.04.01.01.00	Low		2010-06-29
T4- Thyroxine (SBS)	8225-300	8275-300			12.04.01.01.00	Low		2010-06-29
fT3, fT4 & TSH – Free Triidothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
Neonatal Thyroid & Genetics								
NTSH – Neonatal Thyrotropin	3425-300	3475-300			12.04.01.90.00	Low		2005-11-11
NT4 – Neonatal Thyroxine	2625-300	2675-300			12.04.01.12.00	Low		2005-11-11
N 17OHP – Neonatal 17 OH Progesterone	5525-300				12.05.01.07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 90 00	Low		2011-09-26
Autoimmune Thyroid								
Anti-Tg – Anti-Thyroglobulin Antigen	1025-300	1075-300			12.10.03.04.00	Low		2005-11-11
Anti-TPO – Anti-Thyroperoxidase Antigen	1125-300	1175-300			12.10.03.01.00	Low		2005-11-11
Fertility & Prenatal								
LH – Lutropin	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH – Follitropin	425-300	475-300			12.05.01.04.00	Low		2005-11-11
PRL – Prolactin	725-300	775-300			12.05.01.08.00	Low		2005-11-11
PRL – Prolactin Sequential	6025-300	6075-300			12.05.01.08.00	Low		2005-11-11
hCG – Human Chorionic Gonadotropin	825-300	875-300			12.05.02.05.00	Low		2005-11-11
Rapid hCG – Rapid Human Chorionic Gonadotropin	3325-300				12.05.02.05.00	Low		2005-11-11
FSH, LH, hCG, sPRL Combo (VAST)	8325-300	8375-300			12.05.01.90.00	Low		2006-08-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
Steroid								
Cortisol	3625-300	3675-300			12.06.02.04.00	Low		2005-11-11
DHEA-S – Dehydroepiandrosterone sulfate	5125-300	5175-300			12.05.01.02.00	Low		2010-06-29
DHEA - Dehydroepiandrosterone	7425-300	7475-300			12.05.01.02.00	Low		2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of CE-marking
E2 – Estradiol	4925-300	4975-300			12.05.01.03.00	Low		2010-06-29
uE3 – Estriol, Unconjugated	5025-300	5075-300			12.05.02.02.00	Low		2010-06-29
Progesterone	4825-300	4875-300			12.05.01.06.00	Low		2010-06-29
Testosterone	3725-300	3775-300			12.05.01.10.00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12.05.01.10.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone	5225-300	5275-300			12.05.01.07.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone Ext. Range	9925-300	9975-300			12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-Hydroxyvitamin D3	7725-300	7775-300			12.06.03.10.00	Low		2011-09-26
Growth & Bone Metabolism								
hGH - Human Growth Hormone	1725-300	1775-300			12.06.04.02.00	Low		2005-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12.06.03.13.00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2475-300			12.06.01.03.00	Low		2005-11-11
Insulin Rapid	5825-300				12.06.01.03.00	Low		2010-06-29
C-peptide	2725-300	2775-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7375-300			12.06.01.03.00	Low		2005-11-11
Cardiac Markers								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2975-300			12.13.01.02.00	Low		2005-11-11
CTnI – Troponin I	3825-300	3875-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	975-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C-Reactive Protein	3125-300	3175-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3275-300			12.13.01.05.00	Low		2005-11-11
Infectious Diseases								
IgG – Anti/H. Pylori	1425-300	1475-300			15.01.04.03.00	Low		2005-11-11
IgM – Anti/H. Pylori	1525-300	1575-300			15.01.04.03.00	Low		2005-11-11
IgA – Anti/H. Pylori	1625-300	1675-300			15.01.04.03.00	Low		2005-11-11
Cancer Markers								
AFP – Alpha-Fetoprotein	1925-300	1975-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3075-300			12.03.01.06.00	Low		2005-11-11
CA 15-3 Breast Cancer Antigen	5625-300	5675-300			12.03.01.02.00	Low		2010-06-29
CA 19-9 - Pancreatic Cancer Antigen	3925-300	3975-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1875-300			12.03.01.31.00	Low		2005-11-11
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12.03.01.31.00	Low		2010-06-29
fβhCG – Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12.03.01.90.00	Low		2005-11-11
Allergy & Anemia								
Ferritin	2825-300	2875-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7575-300			12.07.01.03.00	Low		2010-06-29
IgE – Immunoglobulin E	2525-300	2575-300			12.02.01.02.00	Low		2005-11-11
sTfR - Transferrin Soluble Receptor	8625-300	8675-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7675-300			12.07.02.04.00	Low		2011-09-26

Miscellaneous Controls								
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase			AIT-101		12.50.01.16.00	Low		2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low		2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estriol			MC-300		12.50.01.16.00	Low		2010-06-29
Thyroglobulin Control – Tri Level			TG-300		12.50.01.16.00	Low		2010-06-29
H. Pylori IgG Control – Positive & Negative			HPy-IgG-300		12.50.01.16.00	Low		2010-06-29
Miscellaneous Instruments								
IC hardware + dedicated accessories + software – Autoplex ELISA Analyzer & CLIA Processor				IN006	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax Chemiluminescence Strip Reader				IN001	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Neo-Lumax Chemiluminescence Strip Reader				IN010	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Impulse 2 Chemiluminescence Strip Reader				IN005	21.02.10.01	Low		2006-08-24
IC hardware + dedicated accessories + software – Impulse 3 Chemiluminescence Strip Reader				IN007	21.02.10.01	Low		2010-06-29
IC hardware + dedicated accessories + software – Lumax96 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low		2007-03-01
IC hardware + dedicated accessories + software – LuMatic Chemiluminescence Plate Reader				IN008	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Eldex 3.8 ELISA Strip Reader				IN003	21.02.10.01	Low		2007-09-10
IC hardware + dedicated accessories + software – Neo-Eldex ELISA Strip Reader				IN009	21.02.10.01	Low		2011-09-26
IC hardware + dedicated accessories + software – Mircoplate Washer				IN002	21.02.10.01	Low		2010-06-29

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name:* DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Para el producto/*For the product*:

Categoría/*Category*: Productos Sanitarios para Diagnóstico "In Vitro" */ In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas */ Diagnostic of infectious diseases*
Tipo/*Type*: Especificados en Anexos de este Certificado/*Specified in Annexes to this Certificate.*

Elaborado en/*In the facilities*:

Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel. (+34) 902 101 322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of*:

Fabricante/*Manufacturer*:
Nombre/*Name:* Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/*Address:* Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/*Authorized EU representative*:
Nombre/*Name:* Idem Dirección/*Address:* Idem

Tipo de producto / *Device type*: **Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas** */ Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/*Classification*: Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)*
[NANDO: IVD 0203]

HBs Ag one Version ULTRA ELISA cualitativo / *ELISA qualitative*

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests - for Dia.Blood application)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel. (+34) 902 101 322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318