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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 28 Juillet 2017

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

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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	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	53251
CREATININE PAP SL	CRSL-0630/0250	DOS-CE-CRSL	53250
DIRECT BILIRUBIN ENVOY	BIDV-0850	DOS-CE-BILI	53233
GLUCOSE ENVOY	GPSL-0850	DOS-CE-GPSL	53301
GLUCOSE HK SL	GHSL-0600/0250	DOS-CE-GHSL	
GLUCOSE PAP	GLUP-0700	DOS-CE-GLUP	
GLUCOSE PAP SL	GPSL-0495/0500/0700/ 0507/0707/0250/0455/0497	DOS-CE-GPSL	
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	53481
PHOSPHORUS	PHOS-0600/0230	DOS-CE-PHOS	59123
PHOSPHORUS ENVOY	PHOS-0850		
TOTAL BILRUBIN ENVOY	BITV-0850	DOS-CE-BILI	53229
TOTAL PROTEIN	PRTB-0600	DOS-CE-PRTB	53985
TOTAL PROTEIN ENVOY	PROB-0850	DOS-CE-PROB	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250		
UREA ENVOY	URSL-0850	DOS-CE-URSL	53587
UREA UV	URUV-0400	DOS-CE-URUV	
UREA UV SL	URSL-0400/0420/0500 0407/0427/0507/0250/0455	DOS-CE-URSL	
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/ 0427/0507/0707/0250	DOS-CE-AUML	
URIC ACID SL	AUSL-0250	DOS-CE-AUSL	

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ELITechGroup
CLINICAL SYSTEMS

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
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CLINICAL SYSTEMS

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		

SOCIETATEA CU RASPUNDERE LIMITATA * ELITech Clinical Systems SAS * REPUBLICA MOLDOVA - CHISINAU

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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 28 juillet 2017

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

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
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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	45789
CALCIUM ENVOY	CALA-0850		
CHLORIDE	CHLO-0600/0250	DOS-CE-CHLO	60037
IRON CHROMAZUROL	FECA-0600	DOS-CE-FECA	54758
IRON ENVOY	FEFE-0850	DOS-CE-FEFE	
IRON FERENE	FEFE-0230		
IRON FERROZINE	FEFR-0600/0250	DOS-CE-FEFR	
MAGNESIUM CALMAGITE	MAGN-0600/0125	DOS-CE-MAGN	46795
MAGNESIUM XYLIDYL	MAGX-0230	DOS-CE-MAGX	
MAGNESIUM ENVOY	MAGX-0850		

SOCIETATEA CU RASPUNDERE LIMITATA "GEC-MLDM" Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHISINAU

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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,
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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		

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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
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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	
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100	41818
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT	47869
ISE CONTROL II	ISCT-0047		
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-PRTU100	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-TRIG200	44702
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-URUV50	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	DOS-CE-ACUR6	44704

ELITech Clinical Systems SAS

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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 11 «ISE SOLUTIONS POUR ELECTRODES SELECTIVES D'IONS », 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 11 "ISE SOLUTIONS FOR ION-SELECTIVE ELECTRODES", 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 11 " ISE SOLUCIONES POR ELECTRODES SELECTIVOS DE IONES", 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

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 11 - ISE SOLUTIONS POUR ELECTRODES SELECTIVES D'IONS
GROUP 11 - ISE SOLUTIONS FOR ION-SELECTIVE ELECTRODES
GRUPO 11 – ISE SOLUCIONES POR ELECTRODES SELECTIVOS DE IONES

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
ISE BASELINE SOLUTION ENVOY	ISBA-0850	DOS-CE-ISE ENVOY	59238
ISE CALIBRATORS	ISCA-0250	DOS-CE-ISE	52867
ISE CALIBRATOR ENVOY	ISCV-0850	DOS-CE-ISE ENVOY	
ISE CLEANER/CONDITIONER	ISCC-0280	DOS-CE-ISE	59058
ISE DILUENT	ISDI-0250		58237
ISE DILUENT ENVOY	ISDV-0850	DOS-CE-ISE ENVOY	
ISE REFERENCE SOLUTION	ISRS-0800	DOS-CE-ISE	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	DOS-CE-ISE ENVOY	

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN.

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 dispositifs appartenant au groupe 12 «SOLUTIONS DE LAVAGE pour équipements ELITech Clinical Systems », 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 d 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 devices belonging to Group 12, "CLEANING SOLUTIONS for ELITech Clinical Systems Equipments", 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 upon the content 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 dispositivos pertenecientes al grupo 12 : " SOLUCIONES DE LIMPIEZA para los equipos ELITech Clinical Systems", 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 está documentada por su contenido de cada DOS-CE-XXXX tecnicá 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

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
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SIREN 318 365 228 RCS ALENCON

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
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www.elitechgroup.com

GROUPE 12 - SOLUTIONS DE LAVAGE pour les équipements ELITech Clinical Systems
GROUP 12 - CLEANING SOLUTIONS for ELITech Clinical Systems Equipments
GRUPO 12 –SOLUCIONES DE LIMPIEZA para los equipos ELITech Clinical Systems

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
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	DOS-CE-SOLVS	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900		
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900		58236

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 22 28 77 51
SIREN 318 365 228 RCS ALENCON

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
"GBG-MLD"
IDNO 1003600117582
REPUBLICA MOLDOVA, MUN. CHIȘINĂU

Société par actions simplifiée au capital de 1 219 592,14€ – SIREN : 318 365 228 – RCS ALENCON

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

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

GMED_SQ_SPE_V0-04-2016

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié par l'autorité compétente française en matière de dispositifs médicaux n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

ISO 9001 -NF EN ISO 13485

ELITechGroup
SEPPIM
REAGENTS

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

TO WHOM TO BE CONCERNED

We, Seppim S.A.S., manufacturers of Elitech Clinical Systems reagents, having our factory at Zone Industrielle, 61500 Sées - France, confirm that our clinical reagents have been validated on Vital Scientific equipment. As such available Elitech Clinical Systems reagent applications for Vital Scientific instruments are CE-IVD compliant.

Reagents, other than Elitech Clinical Systems reagents, are not validated on Vital Scientific equipments, and we also can't know the impact of other reagents on Vital Scientifc equipments.

May 22nd, 2012

Noi, subsemnaţii Seppim S.A.S., compania producătoare a regenţilor Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franţa, confirmăm, că reagenţii au fost testaţi si validaţi pe echipamentele Vital Scientific. Pentru aceşti reagenţi existând şi protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenţii cât şi echipamentele sunt certificate CE-IVD.

Alţi reagenţi înafara de Elitech Clinical Systems, nu au fost testaţi şi validaţi la echipamentele Vital Scientific şi noi nu cunoaştem compatibilitatea şi impactul lor asupra analizatoarelor Vital Scientific.

22 mai 2012

Signed on behalf of the manufacturer
Valérie GOURDON
Regulatory Affairs Manager
COMPANY SEPPIM S.A.S

SEPPIM S.A.S
4 rue Auguste Mottin
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

ELITechGroup
BIOMEDICAL SYSTEMS
370 West 1700 South
Logan, Utah 84321 USA
435 752 6011
800 453 3725
fax 435 752 4127
web www.elitechgroup.com

EC DECLARATION OF CONFORMITY

Manufacturer's Name: ELITechGroup Inc.

Manufacturer's Address: 370 West 1700 South
Logan, Utah 84321 USA

European Authorized Representative: ELITechGroup B.V.
Van Rensselaerweg 4
Spankeren, Gelderland, 6956 AV
The Netherlands

Declares, under sole responsibility, that the following items,

Devices: Ion Selective Electrodes

Description: Solid state ion selective electrodes

Item Number	Product Name	Description	GMDN Code	EDMA Code
3918-002	Reference Electrode	Reference Ion Selective Electrode	59241	11 04 04 01
3918-003	Carbon Dioxide (CO2) Electrode	Indicator Ion Selective Electrode	60773	11 04 02 01
3918-004	Sodium (Na) Electrode	Indicator Ion Selective Electrode	52896	11 04 01 07
3918-005	Potassium (K) Electrode	Indicator Ion Selective Electrode	52892	11 04 01 06
3918-006	Chloride (Cl) Electrode	Indicator Ion Selective Electrode	52876	11 04 01 03
3918-007	Bypass Electrode	Circuit Bypass Electrode	N/A	N/A

Conform to the applicable sections and the Essential Requirements of the European Union Council Directive concerning InVitro diagnostic medical devices, IVDD 98/79/EC Annex I and Annex III. These products are not in List A, List B nor Self-Testing and as such meet the characteristics in the category of Other/General. In addition, these items conform to the European Union Council Directive concerning RoHS 2, 2011/65/EC.

These items bear the IVD and CE markings. IVD CE

Manufacturer's signature
Bryce McEuen

European Authorized Representative's Signature
Adriaan Intveld

Dawn Perdue
Director of Quality Assurance / Regulatory Affairs

Date: 15 May 2017

Location: Logan, UT U.S.A

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

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Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
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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

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Localizador: P6LLDBAA94

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ORGANISMO NOTIFICADO 0318

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agencia española de medicamentos y productos sanitarios

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PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date:* **11/12/2003**
Fecha de última prórroga/ *Last extension date:* **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0391 ED	**Desde/*From* 26/11/2018 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, 23 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

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Fecha de la firma: 23/11/2018
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ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
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A favor de/*In favour of:*

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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]

HBc Ab ELISA cualitativo / *ELISA qualitative*

- BCAB.CE (96 tests)

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, 23 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

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ORGANISMO NOTIFICADO 0318

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Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 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).
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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:*

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Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

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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 — Localizador: B86E8DZ586
Fecha de la firma: 19/11/2018
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ORGANISMO NOTIFICADO 0318

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

PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 11/12/2003
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 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 C, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA)*
[NANDO: IVD 0203]

HCV Ab ELISA cualitativo / *ELISA qualitative*

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.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 — Localizador: B86E8DZ586
Fecha de la firma: 19/11/2018
Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

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Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

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*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 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: GJEC8290C8

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

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Fax (+34) 91 822 52 89

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*: 11/12/2003
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 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 D, mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)*
[NANDO: IVD 0203]

HDV Ab ELISA cualitativo / *ELISA qualitative*

- DAB.CE (96 tests)

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: GJEC8290C8

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

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Avantor Performance Materials Poland Spółka Akcyjna
ul. Sowińskiego 11
44-101 Gliwice, Poland
Tel.: +48 32 239 20 00
Fax: +48 32 239 23 70
e-mail: avantor.pl@avantormaterials.com
www.poch.com.pl
www.avantormaterials.com

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.
June 14, 2016

Anna Szuba
Quality Director

Avantor Performance Materials Poland Spółka Akcyjna
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Tel.: +48 32 239 20 00
Fax: +48 32 239 23 70
e-mail: avantor.pl@avantormaterials.com
www.poch.com.pl
www.avantormaterials.com

Deklaracja zgodności WE

Avantor Performance Materials Poland S.A. producent odczynników do diagnostyki in vitro zlokalizowany:

ul. Sowińskiego 11
44-101, Gliwice
Polska

Deklaruje zgodność odczynników wymienionych w załączonej liście oznakowanych etykietą J.T.Baker z wymaganiami Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady w sprawie wyrobów medycznych używanych do diagnostyki in vitro oraz wymaganiami normy ISO 13485.
Powyższe odczynniki są oznakowane etykietą J.T.Baker i posiadają znaki CE na etykiecie.
Produkty nie są częścią wykazu A i wykazu B załącznika II Dyrektywy dla wyrobów medycznych do diagnostyki in vitro z Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady, ale podlegają rejestracji.
Deklaracja obowiązuje dla wszystkich wyrobów medycznych do diagnostyki in vitro opisanych powyżej oraz wprowadzonych na rynek i posiadających oznakowanie CE.

Gliwice, Polska.
Czerwiec 14, 2016

Anna Szuba
Dyrektor Jakości

NIP: 631-010-13-07
Sąd Rejonowy w Gliwicach, X Wydział Gospodarczy KRS nr 0000010108
Wysokość kapitału zakładowego: 2 360 793,00 zł., w całości opłacony
Trademarks are owned by Avantor Performance Materials, Inc. or its affiliates unless otherwise noted
© 2014 Avantor Performance Materials, Inc.

J.T.Baker product list for CE marked products

Product	Product Number	Pack Size
H32 3-Part Differential	2983	1 unit
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 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
Diluid™ Erma	3459.9020	20 L
Diluid™ Mindray	3439.9020PC	20 L
Diluid™ NR	3483.9020PC	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	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
	3977	5 L
CyMet™ Abacus CN free	3431.1000	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	3.8 L
CyMet™ ASB	2951.0250PE	380 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3964	5 L
	3968	1 L
CyMet™ III Diff CN free	3511.1000	1 L
CyMet™ Erma	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
CyMet™ Mindray CN Free	3440.0500PE	500 ml
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	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
	3768.1000	1 L micros
ProClean™ Abacus	3432.5000	5 L
	3432.1000PE	1 L

J.T.Baker product list for CE marked products

ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862.5000	5 L
	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 L+N+H	3746	3 x 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 4xL	3466	4 x 2.5 ml
3-Diff Control 4xN	3467	4 x 2.5 ml
3-Diff Control 4xH	3468	4 x 2.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
BC-Diff 5 Control L/N/H	3613/3614/3615	3.0 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
10% v/v Buffered Formaldehyde (4% w/v)	3933.5000PC	5 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.9010	10 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.9020	20 L
UltraClear™	3905.2500PE	2.5 L
UltraClear™	3905.5000PE	5 L
UltraClear™	3905.9010PE	10 L
Eosin-Y Alcoholic	3800.1000PE	1 L
Eosin-Y Alcoholic	3800.2500PE	2.5 L
Giemsa	3856.1000	1 L
Giemsa	3856.2500	2.5 L
Hematoxylin er (Mayer)	3870.1000	1 L
Hematoxylin er (Mayer)	3870.2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873.1000	1 L
Hematoxylin Modified (Harris, Gill II)	3873.2500	2.5 L
May-Grünwald	3855.1000	1 L
May-Grünwald	3855.2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
Papanicolaou 2A	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
Papanicolaou 2B	3555.2500PE	2.5 L
Papanicolaou 3B	3556.1000PE	1 L
Papanicolaou 3B	3556.2500PE	2.5 L
UltraKitt™	3921.0500	500 ml
UltraKitt™	3921.0600	6 x 100 ml
Mounting medium High	3882.0500	500 ml
Mounting medium Low	3883.0500	500 ml
PBS	3059	20 L
PBS	3059.9010PC	10 L

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

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
09H46-02	58236	CELL-DYN Emerald CLEANER	**Self-declared**
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	**Self-declared**
09H48-02	58237	CELL-DYN Emerald 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
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:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02. Dec. 2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. ICBG-MLD 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 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:	Kevin Richardson	Full Name:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APR-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. UGB MLD (IDNO 1003600117582) REPUBLICA MOLDOVA, MUN. CHISINAU

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

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
5267L	Thromboplastin L	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: 06 Aug 2015

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-7-0512DC DOI 2015/08 (5)

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
5556	Clauss Fibrinogen 50	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: 12 Aug 2015

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Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0138DC DOI 2015/07 (7)

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: 28 Jul 2015

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info@helena-biosciences.com
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Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0135DC DOI 2015/07 (7)

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: 28 Jul 2015

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Helena Biosciences Europe
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Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0137DC DOI 2015/07 (7)

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: 28 Jul 2015

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Helena Biosciences Europe
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Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0136DC DOI 2015/07 (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
5185	Calibration Plasma	55995

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: 28 Jul 2015

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МЕДИКЛОН

ООО "Медиклон"

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

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ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 40

Годен до: 21.10.2021 **Объем серии:** 10000 мл.

Паспорт: В095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64 Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64 Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

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ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-АВ

Серия: 098611 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 10

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 – 1:64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ - 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

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ООО "Медиклон"

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 292711 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежсвого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микроплате не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product Name	Catalogue Number
Anti-Kell Monoclonal	760010

has been classified as List A (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 the Commission Decision on Common Technical Specifications 2009/108/EC.

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

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.

Eddy Velthuis
Technical Director

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
AGBG-MLDM
S.R.L.
REPUBLICA MOLDOVA, MUN. CHIȘINĂU

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

Lorne Laboratories Limited
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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

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П А С П О Р Т – С Е Р Т И Ф И К А Т ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D (IgG))

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D(IgG)

Серия: 292110 **Единица:** 100 мл

Изготовлен: 28.10.2019 **Количество единиц** 10

Годен до: 28.10.2021 **Объем серии:** 10000 мл.

Паспорт: Дж292110 от 28.10.2019

Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация эритроцитов D+ с Цоликлоном в пробирочном тесте с желатином должна появляться не позднее 15 мин.	Соответствует
2.3 Титр	Титр Цоликлона анти-D в пробирочном тесте с желатином 1:128; Титр Цоликлона в непрямом антиглобулиновом тесте : 1:512	Соответствует

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

МЕДИКЛОН

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ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-Kell Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Kell Супер

Серия: 196410 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 10

Годен до: 21.10.2021 **Объем серии:** 10000 мл.

Паспорт: К196410 от 21.10.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты K(-)	Соответствует
2.2 Гематлютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микроплате не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

To whom it may concern

DECLARATION OF EUROPEAN CONFORMITY

LABORATORY REAGENTS & INSTRUMENTS

I, the undersigned, Mrs Oget Isabelle, Regulatory Affairs Director of BIOLABO S.A.S, certify that our Reagents and Instruments (ACCORDING TO ATTACHED LIST, 5 PAGES) are manufactured by BIOLABO S.A.S in its Maizy facilities (Les Hautes Rives, F-02160, France) for a world-wide distribution including European Union (EU).

1) These products fulfil the essential requirements (Annexe 1) of European Directive IVDMD 98/79/CE.
2) Essential requirements are reviewed by checking the technical files, including the following information :
   - File for checking Essential Requirements of above mentioned European Directive.
   - File for device's design
   - File for performance (technical specifications).
   - Process management (BIOLABO Standard Operating Procedures, ISO 9001:2008 & 13485:2004 certified)
   - Labelling instructions and references.
   - Package inserts instructions and references.
   - File for batches Traceability including customer's information.
   - Risk Analysis, based on EN ISO 14971.
3) BIOLABO S.A.S Quality System Management is ISO 9001:2008 certified under No 1999/12367.10 and ISO 13485:2004 certified under n° 2006/31601.4, by AFAQ (French Association for Quality Assurance)
4) I declare that the above information is true and sincere, certifying the product mentioned above fully comply with European Directive 98/79/CE.
5) I commit myself to provide to competent French Republic authorities any information which would be requested related to this product, whatever is the origin of such request which may come from their foreign homologues.

This Declaration is issued at Maizy, France, on 20 October 2014.

I. OGET
REGULATORY AFFAIRS DIRECTOR

Adress : Les Hautes Rives F-02160 MAIZY (FRANCE) - Phone. : (33) 03 23 25 15 50 - Fax : (33) 03 23 25 82 56
BIOLABO S.A.S with a capital of 119700 € - SIRET 317 396 832 00038 - VAT : FR 82 317 396 832 - NAF 2059Z
WEB : http://www.biolabo.fr - email : info@biolabo.fr

BIOLABO - Désignation des Dispositifs / Devices Designation

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
80002	ALBUMINE Méthode BGC	ALBUMIN BGC 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
92027	ALT/TGP Méthode Colorimétrique	ALT/GPT Colorimetric Method
99523	AMYLASE CNPG3	AMYLASE CNPG3
99123	AMYLASE CNPG3	AMYLASE CNPG3
99223	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
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 & 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 Méthode CHOD-PAP	CHOLESTEROL CHOD-PAP Method
LP80106	CHOLESTEROL CHOD-PAP Liquide Prêt à l'emploi	CHOLESTEROL CHOD-PAP liquid Ready to use
87656	CHOLESTEROL Méthode CHOD-PAP	CHOLESTEROL CHOD-PAP Method
88656	CHOLESTEROL Non estérifié Méthode CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP Method
99656	CHOLESTEROL Non estérifié Méthode CHOD-PAP	Non Esterified CHOLESTEROL CHOD-PAP Method
87356	CHOLESTEROL Méthode CHOD-PAP	CHOLESTEROL CHOD-PAP Method
90205	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) Précipitant
86516	CHOLESTEROL-HDL (PTA) Précipitant	CHOLESTEROL-HDL (PTA) Précipitant
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

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)
92308	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 U.V.)	Lyophilised G6-PDH U.V. Kinetic Method
80110	GAMMA GT GPNA soluble	GAMMA GT Soluble GPNA
80210	GAMMA GT GPNA soluble	GAMMA GT Soluble GPNA
80310	GAMMA GT GPNA soluble	GAMMA GT Soluble GPNA
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 Liquide Prêt à l'emploi	GLUCOSE GOD-PAP Liquid ready for use
LP87809	GLUCOSE GOD-PAP Liquide Prêt à l'emploi	GLUCOSE GOD-PAP Liquid ready for use
3502200	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin)
82250	HEMOGLOBINE Méthode Colorimétrique (Cyanméthémoglobine: 1/50)	HAEMOGLOBIN Colorimetric Method (Cyanmethemoglobin: 1/50)
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	PHOSPHATASES ACIDES Méthode Cinétique	ACID PHOSPHATASE Kinetic Method
3300060	PHOSPHATASES ACIDES Méthode Point Final (PNPP)	ACID PHOSPHATASE End Point Method (PNPP)
99105	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDES Colorimetric enzymatic Method
99110	PHOSPHOLIPIDES Méthode colorimétrique enzymatique	PHOSPHOLIPIDES Colorimetric enzymatic Method
80015	PHOSPHORE Inorganique Méthode U.V.	Inorganic PHOSPHOROUS U.V. Method
80016	PROTEINES TOTALES Méthode Biuret	TOTAL PROTEIN Biuret Method
LP87016	PROTEINES TOTALES Méthode Biuret Prêt à l'emploi	TOTAL PROTEIN Biuret Method Ready to use
97016	PROTEINES U.S. Méthode Rouge de Pyrogallol	U.S. PROTEIN Pyrogaloil Red Method
80019	TRIGLYCERIDES Méthode GPO	TRIGLYCERIDES GPO Method
87319	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
92315	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method
92300	KIT CALCULS URINAIRES Méthode qualitative chimique	STONE ANALYSIS SET Chemical qualitative method

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
95010	BIOLABO EXATROL-N Taux normaux	BIOLABO EXATROL-N Normal values
95011	BIOLABO EXATROL-P Taux pathologiques	BIOLABO EXATROL-P Pathological values
95015	BIOLABO MULTICALIBRATOR Calibrateur Multiparamétrique	BIOLABO MULTICALIBRATOR Multiparametric calibrator
95020	BIOLABO EEQ Evaluation externe de la qualité	BIOLABO EQA External Quality Assesment
95403	BIOLABO CONTROLE PEDIATRIQUE	BIOLABO PAEDIATRIC CONTROL
95406	CALIBRATEUR CHOLESTEROL-HDL	HDL-CHOLESTEROL CALIBRATOR
95806	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/Lipides "Level 1"
95526	Sérum de contrôle HDL/LDL/CK-MB/Lipides "Taux 2"	Control serum HDL/LDL/CK-MB/Lipides "Level 2"
95801	Calibrant LIPASE	LIPASE Calibrator
95013	Contrôle Normal AMMONIAC / ALCOOL / BICARBONATE	Normal Control AMMONIA / ALCOHOL / BICARBONATE
95023	Contrôle Patho. 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 Temps de Quick Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13885	BIO-TP Temps de Quick Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13881	BIO-TP Temps de Quick Taux de Prothrombine (TP)	BIO-TP Prothrombin Time (PT)
13702	BIO-TP LI (Low ISI) Temps de Quick Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13704	BIO-TP LI (Low ISI) Temps de Quick Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13712	BIO-TP LI (Low ISI) Temps de Quick Taux de Prothrombine (TP)	BIO-TP LI (Low ISI) Prothrombin Time (PT)
13883	TAMPON OWREN KOLLER	OWREN-KOLLER BUFFER
13560	BIO-CK Temps de Thromboplastine Partielle activée (TCA)	BIO-CK Activated Partial Thromboplastin Time (APTT)
13570	BIO-CK Temps de Thromboplastine Partielle activée (TCA)	BIO-CK Activated Partial Thromboplastin Time (APTT)
13660	BIO-SIL Temps de Thromboplastine activée (TCA) Méthode silice	BIO-SIL Activated Partial Thromboplastin Time (APTT) Silice Method
13670	BIO-SIL Temps de Thromboplastine activée (TCA) Méthode silice	BIO-SIL Activated Partial Thromboplastin Time (APTT) Silice Method
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 Fibrinoge
13455	TAMPON FIBRINOGENE	FIBRINOGEN BUFFER
13980	BIO-TT Temps de Thrombine	BIO-TT Thrombin Time
13965	TP-CAL/SET SET de Plasmas de Référence Détermination du Taux de Prothrombine (Temps de Quick)	TP-CAL/SET Standard Set For use during the determination of Prothrombin Time (if to be expressed as %)
13970	BIO-CAL Plasma de référence Pour la calibration lors de la détermination du fibrinogène et du Temps de Quick (Taux de Prothrombine %)	BIO-CAL Reference Plasma For use as calibration plasma during the determination of Fibrinogen and Prothrombin Time (if to be expressed as %)
13961	PLASMA CONTRÔLE TAUX NORMAUX	CONTROL PLASMA NORMALVALUES
13962	PLASMA CONTRÔLE TAUX PATHOLOGIQUES HAUTS	CONTROL PLASMA PATHOLOGICAL HIGH VALUES
13963	PLASMA CONTRÔLE TAUX PATHOLOGIQUES BAS	CONTROL PLASMA PATHOLOGICAL LOW VALUES
13210	D-Dimer	D-Dimer
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

REF	DESIGNATION FR	DESIGNATION GB
13308	Facteur VIII – Plasma Déficient	Factor VIII - Deficient plasma
13309	Facteur IX – Plasma Déficient	Factor IX - Deficient plasma
13310	Facteur X – Plasma Déficient	Factor X - Deficient plasma
13971	Control N - Plasma de contrôle Niveau 1 pour l'hémostase	Control N - Control plasma level 1 for coagulation
13972	Control P - Plasma de contrôle Niveau 2 pour l'hémostase	Control P - Control plasma level 2 for coagulation
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	Antigènes Fébriles Pour Tests de Widal Félix (4x5ml)	Stained Febrile Antigens For Widal Felix Tests (4x5ml)
99056	Antigènes Fébriles Pour Tests de Widal Félix (6x5ml)	Stained Febrile Antigens For Widal Felix Tests (6x5ml)
99058	Antigènes Fébriles Pour Tests de Widal Félix (8x5ml)	Stained Febrile Antigens For Widal Felix Tests (8x5ml)
081050	ASLO-LATEX	ASLO-LATEX
097100	CRP-LATEX	CRP-LATEX
098100	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 Rhumatoïdes (RF) – Test Immunoturbidimètrique	RHEUMATOID FACTOR (FR) – Turbidimetric Immunoassay
RF520E	Facteurs Rhumatoïdes (RF) – Test Immunoturbidimétrique	RHEUMATOID FACTOR (FR) – Turbidimetric Immunoassay
RF/CAL_SET51	BIOLABO RF « Kit de Calibration »	BIOLABO RF « Standard Set »
RF/CAL_SH1	BIOLABO RF Calibrant Super Haut	BIOLABO RF Standard Super High
RF/CONT1	BIOLABO RF Contrôle	BIOLABO RF Control
RF/CONT5	BIOLABO RF Contrôle	BIOLABO RF Control
CRP050E	CRP – Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP620E	CRP – Test Immunoturbidimétrique	CRP Turbidimetric Immunoassay
CRP/CAL_SET51	BIOLABO CRP « Kit de Calibration »	BIOLABO CRP « Standard Set »
CRP/CAL_SH1	BIOLABO CRP Calibrant Super Haut	BIOLABO CRP Standard Super High
CRP/CONT_L1	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP/CONT_L5	BIOLABO CRP Contrôle Bas	BIOLABO CRP Control Low
CRP/CONT_H1	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
CRP/CONT_H5	BIOLABO CRP Contrôle Haut	BIOLABO CRP Control High
ASLO050E	ASLO - Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO620E	ASLO - Test Immunoturbidimétrique	ASLO Turbidimetric Immunoassay
ASLO/CAL_H1	BIOLABO ASLO Calibrant Haut	BIOLABO ASLO Standard High
ASLO/CAL_SH1	BIOLABO ASLO Calibrant Super Haut	BIOLABO ASLO Standard Super High

BIOLABO - Désignation des Dispositifs / Devices Designation

REF	DESIGNATION FR	DESIGNATION GB
ASLO/CAL_SET41	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/CAL_SET51	BIOLABO A1B « Kit de Calibration »	BIOLABO A1B « Standard Set »
A1B/CAL_H1	BIOLABO A1B Calibrant Haut	BIOLABO A1B Standard High
A1B/CONT1	BIOLABO A1B Contrôle	BIOLABO A1B Control
A1B/CONT5	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
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	PHOTOMETRE KENZA MAX BioChemisTry	KENZA MAX BioChemisTry PHOTOMETER
KENZA 120TX	KENZA 120TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 120TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240 TX	KENZA 240TX - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE	KENZA 240TX - AUTOMATIC BIOCHEMISTRY ANALYSER
KENZA 240 ISE	KENZA 240ISE - ANALYSEUR AUTOMATIQUE DE BIOCHIMIE avec module ISE	KENZA 240ISE - AUTOMATIC BIOCHEMISTRY ANALYSER with ISE Module
720 ISE	Module ISE	ISE Module
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

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

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

Lorne Laboratories Limited
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www.lornelabs.com

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

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Registered office as above. Registered in England No. 04508747. VAT No. 800 3659 66

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product Name	Catalogue Number
AHG Elite (Green)	435010

has been classified as 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 ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.

Eddy Velthuis
Technical Director

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

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

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KABE LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers*/Händlers**: Name and address of the manufacturer*/distributor**:	KABE LABORTECHNIK GmbH Jägerhofstraße 17 51588 Nümbrecht-Elsenroth Deutschland / Germany

Wir erklären in alleiniger Verantwortung* bzw. aufgrund der uns vom Hersteller vorliegenden Informationen**, dass die In-Vitro-Diagnostika der Produktgruppe /
We declare under our sole responsibility* respectively according to the information of the manufacturer** that the in-vitro-diagnostica of product group

kapillare Blutentnahmesysteme
• **Kapillarblutentnahmesystem (GK)***
• **kapillare Probenbehältnisse aus Kunststoff***
  • Blutgaskapillaren (BK)
  • Hämatokritkapillaren (HK)
  • end-to-end Kapillaren (EK)
• **kapillare Probenbehältnisse aus Glas****
  • Blutgaskapillaren (BK)
  • Hämatokritkapillaren (HK)
  • end-to-end Kapillaren (EK)
  • Mikro-Kapillar-Pipetten mit Ringmarke (RM)
	capillary blood collection systems
	• **capillary blood collection system (GK)***
	• **capillary sample containers made of plastic***
	  • blood gas capillaries (BK)
	  • haematocrit capillaries (HK)
	  • end-to-end capillaries (EK)
	• **capillary sample containers made of glass****
	  • blood gas capillaries (BK)
	  • haematocrit capillaries (HK)
	  • end-to-end capillaries (EK)
	  • micro-capillary pipettes with ring mark (RM)

der Klasse / of class	**Andere IVD-Produkte** **Other IVD-devices**

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	**Richtlinie 98/79/EG Anhang III** **Directive 98/79/EC Annex III**

Nümbrecht-Elsenroth, 26.07.2018

André Kolpe, Geschäftsführer / Managing director

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
D-51588 Nümbrecht-Elsenroth
☎ +49 (0) 2293 / 598

ITALCERT

CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2019-11-06	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. IGBG-MEDSERV Nr. 1 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

CERTIFICATO N° 505DM06

CERTIFICATE N° 505DM06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories. Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2019-11-06	2020-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

SOCIETATE CU RĂSPUNDERE LIMITATĂ * SGQ-MD * Nr.4 IDNO 1003605117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / *Head Office*
Via dell'Industria, 12 – 35020 Arzergrande (PD) - Italia

Unità Operative / *Operative Units*
MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
MEUS S.r.l. - Via dell'Industria, 2 - 16 – 35020 Arzergrande (PD) - Italia
ROLL S.R.L. - Via Leonardo Da Vinci, 24A – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia
VACUTEST KIMA S.r.l. - Via dell'Industria, 12 – 35020 Arzergrande (PD) – Italia
VACUTEST KIMA S.r.l. via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_02_IT

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

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ICIM

CERTIFICATO n. 4264/4

CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GRUPPO VACUTEST KIMA

Sede / *Head Office*

Via dell'Industria,12 – 35020 Arzergrande (PD) - Italia

Unità Operative / *Operative Units*

MEUS S.r.l. - Via Leonardo da Vinci, 24B – 26 – 28 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

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KIMA S.R.L. - Via Leonardo da Vinci, 22 – Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

VACUTEST KIMA S.r.l. - Via dell'Industria,12 – 35020 Arzergrande (PD) – Italia

VACUTEST KIMA S.r.l. via L. Da vInci, 22 Zona Industriale Tognana – 35028 Piove di Sacco (PD) - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

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FEDERAZIONE CISQ

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CISQ is the Italian Federation of management system Certification Bodies.

0449CM_03_IT

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
59878-2009-AQ-MCW-FINAS

Initial certification date:
20 December 2000

Valid:
21 June 2018 - 31 August 2021

This is to certify that the management system of

THERMO FISHER SCIENTIFIC, JCS

Kubinskaya 73, liter A, build.1, Saint-Petersburg, Russian Federation, 196240

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
MANUFACTURING OF LIQUID HANDLING PRODUCTS AND SPECIAL DIAGNOSTIC PLASTICS.

Place and date:
Moscow, 21 June 2018

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL – Business Assurance
Trekhprudny per. 9 build. 2, office 406,
Moscow, Russian Federation

Serguei Groubine
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Keilasatama 5, 02150 Espoo, Finland. TEL: +358 10 292 [illegible] www.dnvgl.com

Dia.Pro
*Dia*gnostic
Bio*Pro*bes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP IgM** CODE: **HPM.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES srl

Rev: 05/2018

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GDC-MLD" Nr.4

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, www.cepartner4u.eu)

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:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

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

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

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2013-09-16
(Place & date of issue (yyyy-mm-dd))

Maarn, NL, 2013-09-16
(Place & date of issue (yyyy-mm-dd))

AShatola

Tony Shatola; QA Director, Monobind Inc.
(name; function and signature of manufacturer)

Olga Teirlinck; Consultant, CEpartner4U BV
(name; function and signature of authorized representative)

vs. 2011-X

Declaration form: Standard ISO/IEC 17050-1:2010

Appendix

Date: 2013-09-16

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Thyroid							
Total Triiodothyronine (tT3) Test System	125-300	175-300			12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (fT3) Test Slystem	1325-300	1375-300			12.04.01.01.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300	275-300			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300	1275-300			12.04.01.02.00	Low	2005-11-11
Thyrotropin (TSH) Test System	325-300	375-300			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300	6075-300			12.04.01.11.00	Low	2010-06-29
T3-Uptake (T3U) Test System	525-300	575-300			12.04.01.06.00	Low	2005-11-11
Thyroxine-Binding Globulin (TBG) Test System	3525-300	3575-300			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300	2275-300			12.04.01.08.00	Low	2005-11-11
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) Thyroid Panel (VAST) Test System	8025-300	8075-300			12.04.01.01.00	Low	2005-11-11
Total Triiodothyronine (tT3 SBS) Test System	8125-300	8175-300			12.04.01.01.00	Low	2010-06-29
Total Thyroxine (tT4 SBS) Test System	8225-300	8275-300			12.04.01.01.00	Low	2010-06-29
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone Free Thyroid Panel (VAST) Test System	7025-300	7075-300			12.04.01.01.00	Low	2010-06-29
Neonatal Thyroid & Genetics							
Neonatal TSH (N-TSH) Test System	3425-300	3475-300			12.04.01.90.00	Low	2005-11-11
Neonatal (N-T4) Thyroxine Test System	2625-300	2675-300			12.04.01.12.00	Low	2005-11-11
Neonatal 17OHP (N-17OHP) Test System	5525-300	5575-300			12.05.01.07	Low	2008-02-01
Neonatal TBG (N-TBG) Test System	8925-300	8975-300			12.04.01.09.00	Low	2013-09-16
Autoimmune Thyroid							
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300	1075-300			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300	1175-300			12.10.03.01.00	Low	2005-11-11
Fertility & Prenatal							
Luteinizing Hormone (LH) Test System	625-300	675-300			12.05.01.05.00	Low	2005-11-11
Follicle Stimulating Hormone (FSH) Test System	425-300	475-300			12.05.01.04.00	Low	2005-11-11
Prolactin Hormone (PRL) Test System	725-300	775-300			12.05.01.08.00	Low	2005-11-11
Prolactin Hormone Sequential (PRLs) Test System	6025-300	6075-300			12.05.01.08.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300	875-300			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (Ext. Range hCG) Test System	8825-300	8875-300			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid	3325-300				12.05.02.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
-hCG) Test System							
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) Fertility Panel (VAST) Test System	8325-300	8375-300			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (VAST) Test System	8525-300	8575-300			12.05.01.90.00	Low	2010-06-29
Pregnancy Associated Plasma Protein - A (PAPP-A) Test System	7925-300	7975-300			12.05.02.10.00	Low	2013-09-16
Steroid							
Cortisol Test System	3625-300	3675-300			12.06.02.04.00	Low	2005-11-11
DHEA-S Test System	5125-300	5175-300			12.05.01.02.00	Low	2010-06-29
Dehydroepiandrosterone (DHEA) Test System	7425-300	7475-300			12.05.01.02.00	Low	2011-09-26
Estradiol (E2) Test System	4925-300	4975-300			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300	5075-300			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300	4875-300			12.05.01.06.00	Low	2010-06-29
Sex Hormone Binding Globulin (SHBG) Test System	9125-300	9175-300			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300	3775-300			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300	5375-300			12.05.01.10.00	Low	2010-06-29
17α-OH Progesterone Test System	5225-300	5275-300			12.05.01.07.00	Low	2010-06-29
17α-OH Progesterone - S! Test System	9925-300	9975-300			12.05.01.07.00	Low	2010-10-18
Growth & Bone Metabolism							
Growth Hormone (hGH) Test System	1725-300	1775-300			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9225-300	9275-300			12.06.03.13.00	Low	2011-09-26
25-Hydroxyvitamin D3 (Vitamin D3) Test System	7725-300	7775-300			12.06.03.10.00	Low	2011-09-26
Diabetes							
Insulin Test System	2425-300	2475-300			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300				12.06.01.03.00	Low	2010-06-29
C-Peptide Test System	2725-300	2775-300			12.06.01.01.00	Low	2005-11-11
Insulin - C-Peptide (VAST)	7325-300	7375-300			12.06.01.03.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300	2975-300			12.13.01.02.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300	3875-300			12.13.01.07.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300	975-300			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300	3175-300			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300	3275-300			12.13.01.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Infectious Diseases							
Anti-H. Pylori IgG Test System	1425-300	1475-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM Test System	1525-300	1575-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA Test System	1625-300	1675-300			15.01.04.03.00	Low	2005-11-11
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300	1975-300			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300	3075-300			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300	5675-300			12.03.01.02.00	Low	2010-06-29
CA -19-9 Test System	3925-300	3975-300			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300	1875-300			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen (CEA) Test System	4625-300	4675-300			12.03.01.31.00	Low	2010-06-29
Free β-Subunit Human Chorionic Gonadotropin (fβhCG) Test System	2025-300	2075-300			12.03.01.90.00	Low	2005-11-11
Allergy & Anemia							
Ferritin Test System	2825-300	2875-300			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300	7575-300			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300	2575-300			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300	8675-300			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (B12) Test System	7625-300	7675-300			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (VAST) Test System	7825-300	7875-300			12.07.01.00.00	Low	2013-09-16
Miscellaneous Controls							
Anti-Thyroglobulin (Anti-Tg), Anti-Thyroperoxidase (Anti-TPO) Control – Positive & Negative			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 (Tg) 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
H. Pylori IgM Control – Positive & Negative			HPy-IgM-300		12.50.01.16.00	Low	2013-09-16
H. Pylori IgA Control – Positive & Negative			HPy-IgA-300		12.50.01.16.00	Low	2013-09-16
Thyroid Binding Globulin (TBG) Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex Generation 2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Lumax CLIA Analyzer				IN001	21.02.10.01	Low	2006-08-24
Neo-Lumax CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Impulse 2 CLIA Analyzer				IN005	21.02.10.01	Low	2006-08-24
Impulse 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
Lumax96 CLIA Analyzer				IN004	21.02.10.01	Low	2007-03-01
LuMatic CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
Eldex 3.8 ELISA Analyzer				IN003	21.02.10.01	Low	2007-09-10
Neo-Eldex ELISA Analzyer				IN009	21.02.10.01	Low	2011-09-26
PrisMAtic ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
Plate Washer Microplate Washer				IN002	21.02.10.01	Low	2010-06-29

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор реактивов для предстерилизационного контроля

Азопирам Ст

ОКП 32.50.50.000

СЕРИЯ 10 1 9

Дата изготовления - ОКТ 2019

Изготовитель **НИИ ИТиМ**, г.Санкт-Петербург

№Показатель	Требования по ТУ	Результаты анализа
1.Внешний вид		
1.1. Реактив А амидопирин	Порошок белого цвета	СООТВЕТСТВУЕТ
1.2. Реактив СА Солянокислый	Порошок белого (от серого до светло-зелёного) цвета	СООТВЕТСТВУЕТ
1.3 Гидроксиламина солянокислый С	Порошок белого цвета	СООТВЕТСТВУЕТ
2.Технические характеристики		
2.1.Чувствительность Азопирамовой пробы на сухих реагентах		СООТВЕТСТВУЕТ
Работоспособная реакция при разведении крови не менее	1:50000	

Заключение: Требованиям ТУ СООТВЕТСТВУЕТ

Начальник ОТК Гавриков К.Е.

СЕРТИФИКАТ КАЧЕСТВА

Настоящим удостоверяется , что тонар, идентифицированный как сухие компоненты реактива для определения скрытой крови при предстерилизационном контроле

Азопирам Ст код:38220000 ТНВЭД

Страна происхождения : Россия

Изготовитель: НИИ ИТиМ

Дата изготовления: - ОКТ 2019

Годен до: ОКТ 2021

№ партии: 10 1 9

Соответствует требованиям:

1 ГОСТ 5822-78

2.СанПин № 8. 01. 013. 03

3. Метолическим указаниям МЗ СССР 28-6/13 от 26,05,1988г.

4. ТУ-6-09-5360-88

Подпись ответственного лица

Клона для Электропроск Сонковеев Т.В. к документу Расходная№ 580450 от 19.11.19 к товару поз. 6

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 **17/970319** Дата выпуска **03.2019** Годен до **04.2021**
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 оранжевых 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 **17/970319** соответствует требованиям ТУ 9398-280-11498242-00

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«4» марта 2019 г.

"Агат-Мед"

SPUNDERE LIMITATĂ S.R.L. "GBG-MLD" №4 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

Копия для Электрогорск Соловьева Т.В. к документу РасходнаяБН № 580450 от 19.11.19 к товару поз. 3