MEDICA

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

AUTHORIZATION LETTER

TO WHOM IT MAY CONCERN:

MEDICA CORPORATION, having facilities at 5 Oak Park Drive, Bedford, MA 01730, USA, do hereby authorize the company:

GBG-MLD SRL
65 Tighina Site
Office 607
Chisinau, MD-2001
Republic of Moldova

to be our **DISTRIBUTOR** for the **EasyLyte®, EasyElectrolytes™, EasyBloodGas™ and EasyStat®** analyzers as well as associated reagents and consumables in **Moldova.**

GBG-MLD SRL is authorized by **MEDICA CORPORATION** to enter tenders and quote for all aforementioned products.

GBG-MLD SRL is authorized by **MEDICA CORPORATION** to present offers on our behalf to tenders placed by the government and other institutions for Medica products and consumables

GBG-MLD SRL responsibilities include sales of the **EasyLyte®, EasyElectrolytes™, EasyBloodGas™ and EasyStat®** analyzers and providing service as well as maintaining a supply of reagents and replacement parts.

GBG-MLD SRL is also authorized to provide warranty service for the Medica **EasyLyte®, EasyElectrolytes™, EasyBloodGas™ and EasyStat®** analyzers.

This authorization is effective immediately and is valid until December 31, 2022, unless revoked earlier in writing by Medica Corporation.

David Hagopian
VP, Sales & Marketing
MEDICA CORPORATION

2/4/2020
Date

MEDICA CORPORATION

MEDICA

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5 Oak Park Drive
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Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

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

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sreeram Sergin

Of Global Bunkering Corp

has completed training for the operation and service of the EasyLyte, EasyBloodGas, and EasyStat analyzers.

MEDICA

November 2nd 2017

Date

Randall Rollins

Signed: Randall Rollins
Technical Service Manager

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

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

ISO 13485:2016

The quality management system is applicable to:

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

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM Accrédité CCN

Calin Moldovean
President

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

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

DECLARATION DE CONFORMITE CE

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

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

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

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

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

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

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

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

(Ver lista adjunta)

Sées, le 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
TEL : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00016

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

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

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

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
ALBUMIN	ALBU-0600/0700/0250	DOS-CE-ALBU	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	

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
TEL : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00016

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

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

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
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00035

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

ELITechGroup
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		

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00035

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

DECLARATION DE CONFORMITE CE

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

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

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

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

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

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

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

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

(Ver lista adjunta)

Sées, le 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

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61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00035

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Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
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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		

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00035

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

DECLARATION DE CONFORMITE CE

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

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

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

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

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

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

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

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

(Ver lista adjunta)

Sées, le 28 Juillet 2017

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

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 225 00026

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

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

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

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
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SIRET 318 365 225 00026

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

DECLARATION DE CONFORMITE CE

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

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

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

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

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

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

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

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

(Ver lista adjunta)

Sées, le 28 Juillet 2017

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

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

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

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

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

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200	44698
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT	44693
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2	44700
ELICAL 2	CALI-0550	DOS-CE-CALI2	47868
ELITROL I	CONT-0060	DOS-CE-ELIT I	47869
ELITROL II	CONT-0160	DOS-CE-ELIT II	
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
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

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

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

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
TEL : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

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

GROUPE 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
TEL : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51

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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

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 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

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

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, subsemnații Seppim S.A.S., compania producătoare a regenților Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franța, confirmăm, că reagenții au fost testați si validați pe echipamentele Vital Scientific. Pentru acești reagenți existând și protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenții cât și echipamentele sunt certificate CE-IVD.

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați și validați la echipamentele Vital Scientific și noi nu cunoaștem compatibilitatea și 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
VITAL

Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

Participant: Mr. S. Sorocovici

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

Date of training: April 20th – April 23rd, 2010

System Support Manager:

Jan Oostendorp

System Support Engineer:

Frank v.d. Korput

Spankeren, 17 April 2013

ELITechGroup
VITAL
SCIENTIFIC

P.O. Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands
Tel: +31 313 430500
Fax: +31 313 427807
Email: info@vital.nl
Website: www.vitalscientific.
Vat no.: NL801339650B01

CONFIRMATION LETTER

To whom it may concern,

Vital Scientific B.V., manufacturers of clinical chemistry analyzers having headquarters and factory at:

Van Rensselaerwerg 4,
6956 AV Spankeren/Dieren
The Netherlands

and being a company of ELITech Group, hereby confirms that clinical chemistry analyzer **Selectra ProM** is a closed system. We can guarantee the performance of the analyzer only when ELITech clinical chemistry reagents are used.

Vital Scientific B.V.

Vital Scientific BV
P.O. Box 100 - Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands

A. Altink
Managing Director

Declaration of Conformity

We: ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	**: Clinical chemistry analyzer**
Product No.	**: 6003-400**
Model	**: Selectra ProM**
GMDN code	**: 56678**

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All other member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink

Managing Director

CE Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Certification by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

ELITechGroup
SOLUTIONS
tailored to your needs

ELITechGroup B.V.
P.O. Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands
Tel.: +31 313 430 500
Fax: +31 313 427 807
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

Spankeren, July 20th, 2015

MANUFACTURER'S AUTHORIZATION LETTER

National Competitive Bidding (NCB) No.: 15/01496 Automatic Bio Chemistry Analyzer
For procurement of various medical equipment including biochemistry units.

To:
Agentia Medicamentului si Dispozitivelor Medicale

WHERE AS

We **ELITECHGROUP B.V.** who are official manufacturers of Clinical Chemistry Analyzers having factories at the Van Rensselaerweg 4 * 6956 AV Spankeren * The Netherlands do hereby authorize.

GBG-MLD SRL
mun. Chisinau
str. Tighina 65 of. 607
MD-2001
Republica Moldova

To submit to submit a tender the purpose of which is to provide the following Goods, manufactured by us:

Tender	Item S.I. No.	Description	Required Quantity
15/01496	6003-400	Bio-Chemistry Auto Analyzer Selectra ProM (6 open systems with ISE) (5 closed systems with ISE)	11

Manufactured by us, and to subsequently sign the contract fot the supply of such goods;
We extend our full guarantee and warranty as stated under GCC Clause 27 of the General conditions of contract with respect to Goods offered by the above Tender.

Kind regards,

ELITechGroup B.V.

ELITechGroup B.V.
P.O. Box 100 – 6950 AC Dieren
Van Rensselaerweg 4 – 6956 AV Spankeren
The Netherlands

A. Altink
Managing Director

DEKRA

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

Declaration of conformity

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

Sowińskiego 11 Street
44-101, Gliwice
Poland

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

Gliwice, Poland

January 25, 2019

Anna Szuba

Anna Szuba
Quality Director

NIP 631-010-10-37
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

AVANTOR
PERFORMANCE MATERIALS

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml
3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
Cleaners		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	4 liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1 liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
Reagents for 5-part WBC diff. on STKS and MaxM.		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	Reticount™	30 ml
3747	Reticount CD	15 x 3.5 ml

AVANTOR
PERFORMANCE MATERIALS

Hematology Controls		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L,1 x N,1 x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L,N,H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers:		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline,		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
	Stains and Dyes	
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2,5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2.5 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
	Clearing agent	
3905.2500PE	UltraClear	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
	Mounting media	
3921.0500	UltraKitt	500 ml
3921.0600	UltraKitt	6 x 100 ml
	Fixatives	
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 Liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

H. Shimosaka

Hiroshi Shimosaka
President
ERMA INC.

BeneSphera™
3 PART
DIFFERENTIAL
Hematology Analyzer

BeneSphera TRAINING

Mr /-Ms **Sergiu Sorocovici**

Global Biomarketing Group

str. Tighina 65, of. 607

2001 Chisinau, Moldau

has attended a 2-days training on goods manufactured or distributed by us.

April 12th – April 13th, 2012

Deventer, The Netherlands

Place, Date 13.04.2012

BeneSphera | AVANTOR PERFORMANCE MATERIALS

201

DIA. PRO | Dia.Pro *Dia*gnostic Bio*Pro*bes

Letter of Authorization

We, **"Dia.Pro Diagnostic Bioprobes S.r.l."** located at Via G. Carducci, Nr. 27 – **Sesto San Giovanni (Milan) 20099, Italy**, authorize

GLOBAL BIOMARKETING GROUP – MOLDOVA SRL
Str. Tighina 65, Oficiu 607
MD-2001 CHISINAU
REP. MOLDOVA

as our exclusive distributor for the territory of the Republic of Moldova, to participate in various tenders with **Dia.Pro** ELISA products.

We, Dia.Pro Diagnostic Bioprobes S.r.l shall supply our distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL with all products in strict compliance with the existing "Distribution Agreement" rev.0117 valid until 31-Dec-2020, with possibility of renewal upon agreement between both parties for an additional period.

Dia.Pro Diagnostic Bioprobes S.r.l will grant the supply of all awarded tenders until their natural expiry, of which a documental proof has to be provided to Dia.Pro by the distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL.

Date: **Milan, 31-January-2018**

Sincerely yours,

Dia.Pro Diagnostic Bioprobes S.r.l.
DIA.PRO. DIAGNOSTIC BIOPROBES S.r.l.

Dr.ssa Fiorenza Scozzesi
Legal Representative

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

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Fecha de la firma: 19/11/2018
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CORREO ELECTRÓNICO
on0318@aemps.es
C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

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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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CORREO ELECTRÓNICO
on0318@aemps.es
C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

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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 0390 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

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Fecha de la firma: 19/11/2018
Localizador: 62Y62AG59D

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CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

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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.*

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[NANDO: IVD 0203]

HBs Ab ELISA cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- SAB.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

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Fecha de la firma: 19/11/2018
Localizador: 62Y62AG59D

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28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

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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 N° 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 Diaz

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Fecha de la firma: 23/11/2018
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CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

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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

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 Diaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios — Localizador: RP3FCJG870
Fecha de la firma: 23/11/2018
Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

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 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

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 Diaz

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

CORREO ELECTRONICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE
EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC
PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date*: 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 Diaz

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

CORREO ELECTRONICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902 101 322 /(+34) 91 822 59 97
Fax: (+34) 91 822 52 89

ORGANISMO NOTIFICADO 0318

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: GJEC829008

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

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59.97
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

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 902.101.322 /(+34) 91.822.59 97
Fax: (+34) 91.822.52 89

LORNE LABORATORIES

Date: 21-01-20

To Whom It May Concern

Letter of Authorisation

This is to confirm that GBG-MLD SRL of str. Tighina 65, of 607, MN-2001, Chisinau, Republic of Moldova is an authorised distributor for Lorne Laboratories Limited in Moldova.

GBG-MLD SRL is authorised to present proposals, offer quotations, accept orders and participate in tender number 18/0003 for the National Blood Transfusion Center for products on behalf of Lorne Laboratories Limited. This authorisation is valid until 31.12.2021.

The undersigned herewith states that the above is true and correct.

LORNE LABORATORIES LIMITED
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT
United Kingdom

Ian John
Managing Director

And duly authorised to sign this Authorisation on behalf of Lorne Laboratories Limited

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

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

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product name	Catalogue number
CRP Latex kit	850100A

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

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

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

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

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

Eddy Velthuis
Technical Director

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

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

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

Registered office as above. Registered in England No. 04540797. VAT No. 830 3655 66

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product name	Catalogue number
RF Latex kit	830100A

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

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

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

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

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

Eddy Velthuis
Technical Director

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

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

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product name	Catalogue number
ASO Latex kit	031100A

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

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

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

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

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

Eddy Velthuis
Technical Director

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Unit 1 Cutbush Park Industrial Estate
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Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
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LORNE
LABORATORIES

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
TPHA Microtitre plate kit	043100A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply 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).

This declaration is valid from 17 May 2015.

Eddy Velthuis
Technical Director

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

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

LORNE LABORATORIES

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply 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).

This declaration is valid from 17 May 2015.

Eddy Velthuis
Technical Director

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

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www.lornelabs.com

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

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

Всем заинтересованным лицам

Авторизационное письмо

Настоящим, мы, компания «HELENA LABORATORIES (UK) Ltd», торгующая как «HELENA BIOSCIENCES EUROPE», с центральным офисом по адресу: Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NEll OSD, Великобритания, подтверждает, что:

Компания "GBG-MLD" SRL, республика Молдова, г. Кишинёв, MD-2001, улица ChisinauTighina, дом 65, офис 607 являются уполномоченными дистрибьюторами всей продукции компании «HELENA BIOSCIENCES EUROPE» на территории Республики Молдова и авторизована принимать участие во всех тендерах.

Компании **"GBG-MLD" SRL** имеет право импорта, продвижения и продажи выше перечисленной продукции на территории Республики Молдова.

Настоящее письмо действительно до 31 декабря 2020 года.

Дата: 22/01/2020

Дмитрий Александров

Директор по развитию бизнеса в странах СНГ, Европы и Азии.

Helena Biosciences Europe
Gateshead NE11 0SD, U.K.
www.helena-biosciences.com
Mobile: +44 7515328211
Phone: +44 1914828462
Email: da@helena-biosciences.com

bsi.

By Royal Charter

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number: **MD 69326**

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

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

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

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

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

...making excellence a habit.™

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

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-7-0136DC 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

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-7-0137DC 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

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-7-0138DC 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

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- 0640DC DOI 2015/07 (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
5504R	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: 30 Jul 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-7-0674DC 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
5552	Auto Blue D-Dimer 400	47346

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: 11 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

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул, 35 , т\ф (495) 231-2272, (499) 502-12-14
e-mail : Mediclone@mediclone.ru

ИНН 7719191607 Р/с **40702810038040106975** в ПАО Сбербанк г.Москва, К/С 30101810400000000225 КПП 771501001 БИК 044525225 ОКПО 51203590 ОГРН 1027700153766

Исх 74-19
24.12.2019

СВИДЕТЕЛЬСТВО
НА ЭКСКЛЮЗИВНОЕ ПРАВО ПРОДАЖИ

Общество с ограниченной ответственностью «МЕДИКЛОН» 127276 Россия Москва ул.Ботаническая, 35, ОГРН 1027700153766 - производитель реагентов для трансфузиологии (Цоликлонов) в лице генерального директора Викторова Н.А. официально удостоверяет, что фирма IM «GBG-MLD» SRL , расположенная по адресу : MD-2001 г Кишинёв, ул.Тигина , 65 , оф. 607 , Республика Молдова , является официальным дистрибьютором (авторизованным дилером) всей продукции производства ООО «МЕДИКЛОН» на всей территории Республики Молдова.

IM «GBG-MLD» SRL имеет право на распространение (реализацию), продвижение (рекламу) а также поддержку продукции, выпускаемой фирмой ООО «МЕДИКЛОН» в Республике Молдова.

IM «GBG-MLD» SRL имеет право участвовать от имени фирмы ООО «Медиклон» в частных и Государственных тендерах и тем самым действовать как официальный представитель фирмы ООО «Медиклон» на всей территории Республики Молдова

ООО «Медиклон» распространяет свои полные гарантии на продукцию, проданную фирмой IM «GBG-MLD» SRL .

Генеральный
директор ООО «Медиклон» Н.А.Викторов

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

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
(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 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

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

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(III) 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

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

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 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(III) 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