CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 7

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS

Zone Industrielle

61500 SEES FRANCE

pour les activités

for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.

réalisées sur le(s) site(s) de

performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **July 28th, 2020 (included)**

Valable jusqu'au */ Expiry date :* **July 27th, 2023 (included)**

Etabli le */ Issued on :* **July 17th, 2020**

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.22 12:18:25 EET
Reason: MoldSign Signature
Location: Moldova

On behalf of the President
Lionel DREUX
Certification Director

GMED N° 10462–7

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-6

Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

ELITech Clinical Systems
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 référencés dans la liste ci-jointe (2 pages), 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.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , 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.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each 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 , 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), 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.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico 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 2023).

Sées, le 29 juillet 2020

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

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP SL	CRSL-0630/0250	53250
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN ENVOY	PROB-0850	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA ENVOY	URSL-0850	53587
UREA UV SL	URSL-0407/04270420/0500/0507/0250/0455	
URIC ACID ENVOY	AUVD-0850	53583
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE ENVOY	AMSL-0850	52940
AMYLASE SL	AMSL-0390/0400/0230	
AST ENVOY	ASVD-0850	52954
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL	CMSL-0410/0430/0230	
CK NAC SL	CKSL-0410/0430/0230	53003
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53027
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH-L SL	LLSL-0400/0420/0230	
LIPASE ENVOY	LPSL-0850	53108
LIPASE SL	LPSL-0230	
Electrolytes - Oligo-élements / Electrolytes - Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL ENVOY	CHSL-0850	53359
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
HDL CHOLESTEROL	CHDL-0250/0600	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES ENVOY	TGML-0850	53460
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

CERTIFICATE

Number: 2145682

The management system of the organization(s) and locations mentioned on the addendum belonging to:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

including the implementation meets the requirements of the standard:

ISO 9001:2015

Scope:
The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods.
The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods.

Certificate expiry date: 7 January 2023
Certificate effective date: 31 January 2020
Certified since: 1 October 2013

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 2145682

The management system of the organization(s) and/or location(s) of:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

Certified organization(s) and/or locations:	Different scope
ELITechGroup S.p.A. Corso Italia 22 20122 Milano Italy	Registered office without operational responsibilities
ELITechGroup S.p.A. Corso Svizzera 185 10149 Torino Italy	The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods. The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods

Addendum expiry date: 7 January 2023
Addendum effective date: 31 January 2020

KEMA Quality

CERTIFICATE

ELECTROMAGNETIC COMPATIBILITY

Applicant	:	**Vital Scientific B.V.**
Contact person	:	**Mrs. C. v.d. Broek**
Address	:	**Van Rensselaerweg 4**
Postal code, Place	:	**6956 AV Spankeren/Dieren**
Country	:	**The Netherlands**
Manufacturer	:	**Vital Scientific B.V.**
Address	:	**Van Rensselaerweg 4**
Postal code, Place	:	**6956 AV Spankeren/Dieren**
Country	:	**The Netherlands**
Electrical apparatus	:	**Clinical Analyser**
Trademark	:	**Elitech Clinical Systems**
Type designations	:	**Flexor EL200, Selectra ProM**

Environment : **Laboratory**

EN 61326-1:2006 : Equipment for measurement, control and laboratory use

EN 61326-2-6:2006 : Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: particular requirements – In vitro diagnostic (IVD) medical equipment, from which:

EN 55011:2007 +A2:2007	: Emission - Class A
EN 61000-3-2:2006	: Limit for harmonic currents emissions
EN 61000-3-3:1995 +A1:2001+A2:2005	: Limitation of voltage fluctuations and flicker
EN 61000-4-2:1995 A1:1998+A2:2001	: Electrostatic discharge (ESD) immunity
EN 61000-4-3:2006 +A1:2008	: Radiated Electro-Magnetic field immunity
EN 61000-4-4:2004	: Electrical fast transient (EFT) immunity
EN 61000-4-5:2006	: Surge transient immunity
EN 61000-4-6:2007	: Conducted Radio-Frequency disturbances immunity
EN 61000-4-8:1993 +A1:2001	: Power frequency magnetic field immunity
EN 61000-4-11:2004	: Voltage dips and interruptions immunity

The undersigned declares that the described product meets the requirements of the mentioned standards, based on a non-recurrent examination. The test results lay down in our test reports with reference 2129388.0501-QUA/EMC and 2136226.0501-QUA/EMC.

KEMA Quality B.V.
(Notified Body EMC)
Arnhem, September 20, 2010

A.T. van der Meijden
Certification Manager EMC

Certificate nr. **2136226.0551-QUA/EMC**

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM REAGENTS

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

TO WHOM TO BE CONCERNED

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

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

May 22nd, 2012

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

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

22 mai 2012

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

SEPPIM S.A.S
4 rue Auguste Mottin
Zone Industrielle
61500 SEES – FRANCE
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info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

ELITechGroup
CLINICAL SYSTEMS

Part number	Description	IVD medical device	IVD accessory	general laboratory use	spare part	supporting part
1540-001	Anti-Slip sheet					✓
2206-007	Cooling Liquid (1 L)					✓
3062-021	Sample cup (1000 pcs)		✓			
3062-033	Sample tube 6 ml (500 pcs)					✓
3062-040	Water container 10 L					✓
3062-041	Water container 5 L					✓
3066-155	Syringe 100 µl		✓			
3066-156	Syringe 1 ml		✓			
3069-040	Keyboard Dust cover					✓
3069-047	Keyboard Dust cover					✓
3070-518	Cap holder					✓
3070-538	Cap rotor Left					✓
3070-539	Cap rotor right					✓
3201-002	Dichromate 8 Abs (25ml)		✓			
3365-192	USB Stick					✓
3374-003	Mains cable (USA)					✓
3374-059	Pumpunit cable		✓			
3374-066	Mains cable					✓
3374-097	Serial Null-modem cable					✓
3374-286	USB Extension cable					✓
4804-038	Reagent identification Disc					✓
6001-826	Diluted Waste container		✓			
6001-827	Concentrated Waste container		✓			
6001-860	Water container		✓			
6001-861	Tube assy (analyser)		✓			
6001-872	Tube assy (cooling unit)		✓			
6002-102	Assorter unit				✓	
6002-386	System software on CD		✓			
6002-706	Reaction Rotor set (3 pcs)		✓			
6002-726	System Disc		✓			
6002-817	Bottle 30 ml (20 pcs)		✓			
6002-818	Bottle 15 ml (20 pcs)		✓			
6002-904	Water container 5 L		✓			
6002-910	Assorter unit				✓	
6002-913	External tubing		✓			
6003-074	System software on USB stick		✓			
6003-444	Diluted Waste Container 5 L		✓			
6003-466	Keyboard Support option					✓
6003-797	CW Waste Container 2 L		✓			
6003-808	Assorter unit				✓	

ELITechGroup
VITAL
SCIENTIFIC

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. A. Legun

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

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 accessories) and to which this declaration relates, conforms to the provisions of:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ("IVD Directive")
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS2 Directive")

It is certified that this product is registered in accordance with the requirements of above mentioned EU Directives and carries the CE marking.

Product	**Clinical chemistry analyzer, automated**
Model	**Selectra ProM**
Reference numbers	**6003-400** (Break-in number from 17-7503)
GTIN	**03661540600302**
GMDN code	**56678**
Accessories	**See Annex**

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 IVD Directive
- Article 4 of the RoHS2 Directive

Spankeren, January 2018

Maurice Verdaasdonk

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control and laboratory used – Part 2-010: particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2015	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 61010-2-101:2015	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 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	
	IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

Declaration of Conformity

Annex – List of IVD accessories

EGBV PART NUMBER	DESCRIPTION
3201-019	Precision Test Solution

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

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.	

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

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

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número

grants the certificate no.

2013 11 0039 EN

según la norma

in accordance with the standard

UNE-EN ISO 13485: 2018

(EN ISO 13485: 2016 & ISO 13485: 2016)

Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios

Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa

to the company

Dia.Pro Diagnostic Bioprobes S.r.l.

Sede social y de fabricación/ *Headquarters and manufacturing facility*

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

Para las siguientes actividades / *For the following activities:*

Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.

Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.

Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.

Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.

Modificaciones de alcance/ *Scope modifications:*: **Ver Anexo I /** *see Annex I*
Fecha de validez/ *Date of validity:* **Desde/** *From:* **25-02-2021** **Hasta/***To:* **18-11-2023**
Certificación inicial/ *Initial certification date:* **27-11-2013**
Renovaciones / *Renewal of certification dates:* **8-03-2019; 25-02-2021**

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

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

ANEXO I / *ANNEX I*

CERTIFICADO UNE-EN ISO 13485: 2018/ *UNE-EN ISO 13485: 2018 CERTIFICATE*

Modificaciones del alcance / *Scope modifications:*

Fecha/*Date*	**Descripción de la modificación**/ *Modification description*
18-12-2018	Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico *Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques).* *Change in the level of detail of the technological scope description.*
8-03-2019	Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro". *Extension of technological scope:* *Immunochemistry and Microbiology* *Instruments and software for "in vitro" diagnostic* *Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic*

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

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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 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

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: 62Y62AG59D

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

CORREO ELECTRÓNICO
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ORGANISMO NOTIFICADO 0318

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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

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 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

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ORGANISMO NOTIFICADO 0318

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

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

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

Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 23/11/2018
Localizador: RP3FCJG870

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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

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Localizador: RP3FCJG870

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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 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).

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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: B86E8DZ586

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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 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

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

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

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

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

HCV Ab ELISA cualitativo / *ELISA qualitative*

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

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

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

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: B86E8DZ586

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

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

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

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

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

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0393 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de /*In favour of:*

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

Para el producto/*For the product:*

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

Elaborado en/*In the facilities:*

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

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

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

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

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 19/11/2018
Localizador: GJEC8290C8

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CORREO ELECTRÓNICO
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ORGANISMO NOTIFICADO 0318

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28022 MADRID
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Fax: (+34) 91.822.52.89

CERTIFICADO DE EXAMEN CE DE DISEÑO
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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 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

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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*: **15/03/2004**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2004 03 0425 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).

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Madrid, 23 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 23/11/2018
Localizador: 3P6PS5XA6C

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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]**

HBe Ag & Ab ELISA cualitativo / *ELISA qualitative*

- HBE.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

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agencia española de medicamentos y productos sanitarios

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

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

A favor de /*In favour of:*

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

Para el producto/*For the product:*

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

Elaborado en/*In the facilities:*

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

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

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

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

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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

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Fax: (+34) 91.822.52.89

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

EC DESIGN-EXAMINATION CERTIFICATE
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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*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**0318**

A favor de/*In favour of:*

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

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

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

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

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

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

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

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

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

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Fax: (+34) 91.822.52.89

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

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

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

CERTIFICATO N° 505DM07

CERTIFICATE N° 505DM07

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

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

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MINISTERUL SĂNĂTĂŢII
AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ МОЛДОВА
AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chişinău, str. Gheorghe. Asachi, 67-a
Tel. + 373 22 574501, fax + 373 22 729725
IDNO 1018601000021
E-mail: office@ansp.gov.md

DOCUMENTAŢIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MS al RM / Утверждена МЗ РМ **31.10.11 Nr. 828**

Centrul de încercări de laborator acreditat de către
Centrul Naţional de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный
Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2018 valabil până la 16.02.2022

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ŞI NEALIMENTARE Nr. 5033

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 20. " 12. a./*г.* 2021

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Cutii din carton

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

Regulamentului sanitar privind materialele şi obiectele destinate să vină în contact cu produsele alimentare aprobat prin HG nr.308 din 29.04.2011, GOST 7376-89, GOST 9142-90, GOST 13512-91, GOST 13511-2006, GOST 13516-86, GOST 13513-86

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

„ATGAIA-SU" SRL , Republica Moldova; ООО "ДУНАПАК ТАВРИЯ", Ucraina – furnizor materie primă

Destinatarul avizului sanitar / *получатель санитарного заключения*

„ATGAIA-SU" SRL, Moldova, Chişinău, bd. Dacia, 19, ap.11

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr.201 din 20.11.2020, facturi, certificate de calitate, declaraţie de conformitate, aviz sanitar nr.P-2363/2019 din 31.07.2019, raport a încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

(a enumera documentele însoţire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.)*

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)*	**Normativul sanitar /** *санитарный норматив*

conform raportului încercărilor de laborator nr.8601 din 03.12.2021, din 15.12.2021

Domeniu de utilizare / *Область применения:* ambalaj, inclusiv produse alimentare

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*
producerea, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 31 decembrie 2024

DIRECTORUL AGENŢIEI NAŢIONALE PENTRU SĂNĂTATE PUBLICĂ
Nicolae JELAMSCHI
(numele, prenumele/ Ф.И.О.) (semnătura / подпись)

L.Ş.

ANSP/HAO3

SP 10-XVI-09 0004158 03

ex:Şt.Constantinovici
tel: 574 679

HOLTSCH Medizinprodukte GmbH
In den Faltern 13 • D – 65232 Taunusstein
Germany

Declaration of conformity

This is to confirm that

the swab dispenser **Quickpad®**
containing fleece swabs, saturated with 70% isopropyl alcohol (V/V)

is

manufactured, packaged and sterilized in accordance with the rules of GMP and the paragraph 13 of the GERMAN MEDICAL LAW.

These swabs are equal to a
Medical Device Class I (UMNDS Code15-252)
and are checked and released

conform to

the German Medical Product Law according to

the
Medical Device Directive 93/42/EEC
of the European Counsel.

Taunusstein, November 17th , 2021

HOLTSCH Medizinprodukte GmbH

HOLTSCH
Medizinprodukte GmbH
In den Faltern 13 · 65232 Taunusstein

Malte Hertzberg
(Certified Biologist)

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sorocovici Sergiu

Of Global Biomarketing Group

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

November 25, 2004

Date

MEDICA CORPORATION CORPORATE SEAL MASSACHUSETTS 1965

MEDICA

Randall Rollins

Signed: Randall Rollins
Technical Service Manager