Republica Moldova
mun. Chişinău, MD-2001

str. Tighina 65, of. 607
tel/fax.: (373-22) 54-91-21
tel./fax: (373-22) 54-73-73
tel: (373-22) 54-91-20

GLOBAL BIOMARKETING GROUP - MOLDOVA

Rechizitele bancare:
Cod fiscal/1003600117582
Cod TVA: /0205086
BC "Moldova-Agroindbank"SA
filiala M.Eminescu
cod: AGRNMD2X864
cod IBAN: MD14AG000000225184801542

DECLARATIE

Prin prezenta, va informam ca dezinfectatii al producatorului Alpro Medical GMBH, Germania:

1.DesNet+
2. PlastiSept eco
3. MinutenSpray
4.MinutenWipes
5.BIB forte eco
6.PrintoSept-ID
7.AlproJet-D
8.AlproJet-DD
9.AlproJet-W
10.Alpron
11.Bilpron

sunt inregistrate la Agentia Medicamentului si Dispozitivelor Medicale moldova si puteti sa le gasiti in registrul se stat(print screen este atasat).

Director
"GBG MLD" SRL
Tudor Ceaicovschi

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" S.R.L. IDNO 1003600117582 Nr.2 REPUBLICA MOLDOVA, MUN. CHIŞINĂU

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

Gbg Srl Moldova | ALPRO | Home | Google Переводчик | 89.32.230.138:8081

89.32.230.138:8081

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declarații de conformitate CE

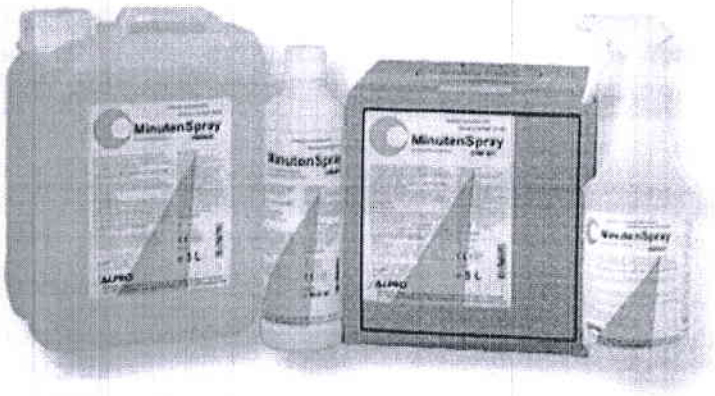
Nr	Denumire	Descriere	Model	Nr. catalog	Țara	Producător	Reprezentant	Ordin	Data	Cod vamal
						Alpro Medical				
DM000026517	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENWIPES 30X30			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026575	DEZINFECTANT PENTRU CURĂȚAREA INSTRUMENTELOR MEDICALE ȘI CHIRURGICALE	BIB FORTE ECO			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026522	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	BILPRON			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026512	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	DESNET ÷			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026529	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	ALPRON			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026515	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENSPRAY-CLASSIC			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026511	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	ALPROJET-DD			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026521	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PRINTOSEPT-ID			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026516	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENWIPES			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	
DM000026519	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PLASTISEPT-ECO			Germania	ALPRO MEDICAL GMBH	GBG-MLD SRL	A07.PS-01.Rg04-229	06-11-2017	

IDNO 1003600117252 Nr.4 «GBG-MLD» S.R.L. REPUBLICA MOLDOVA, MUN.

ROU 12:44 03.04.2018

MinutenSpray

Pentru dezinfectare rapidă *classic*



Preparat special pentru dezinfectarea şi curăţarea rapidă a suprafeţelor dispozitivelor medicale precum piesele de mână sau contraunghi, măsuţa unitului şi echipament divers sau mobilier din cabinet sau laborator.

- lipsit de aldehide şi fenoli
- soluţie gata preparată
- certificare VAH/DGHM

Spectrul de activitate:

- bactericid (incl. TBC, MRSA), fungicid (Candida albicans) în 1 min.
- virucid conform DVV 2012, carrier test în conditii de practica. Este eficace impotriva virusilor non incapsulati în 2 minute (în special adeno-si virusi noro) si toti virusii incapsulati în 30 de secunde (inclusiv HBV, HCV, HIV, herpes simplex, gripa, i virusul rujeolic, inclusiv coronavirusul si MERS-CoV).

Utilizare:

Pulverizaţi de la o distanţă de 30 cm şi lăsaţi să şi facă efectul. Apoi ştergeţi cu un şervetel de unică folosinţă (ex. MinutenWipes).

A se folosi doar pe suprafeţe rezistente la alcool.

Pentru curăţarea şi dezinfectarea suprafeţelor sensibile la alcool vă rugăm să utilizaţi produsul PlastiSept eco.

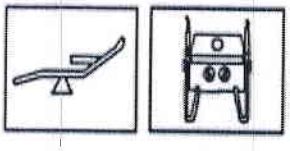
Expertize ştiinţifice:

Prof. Dr. R. Schubert, Frankfurt/M., VAH inkl. EN 13624 + EN 13727, 2006-05 • Prof. Dr. H.-P. Werner, Schwerin, VAH, 2009-09; virucid conform DVV (2012), 2013-11 • Dr. H. Brill, Hamburg, EN 14561 + EN 14562, 2009-06; MRSA, 2009-07; efect de lunga durata/remanenta incl. EN 13697, 2008-01 • Prof. Dr. P. Heeg, Tübingen, DGHM, 1999-03 • Dr. J. Höffler, Hamburg, EN 1040, 2009-05; EN 1275 + EN 1276, 2009-04 • Dr. J. Steinmann, Bremen, BVDV, 2003-11; Vaccinia, 2006-05; Adeno, 2006-05; coronavirus inkl. MERS-CoV, 2014-05

Compoziţie:

100 g conţin:

45 g etanol, 15 g isopropanol, 0,1 g clorhexidina-digluconat, 0,08 g propionat de trialchiletoxi-amoniu, 0,05 g derivate de alchilamine



Observatii speciale:

Atenţie. Lichid şi vapori inflamabili. Provoacă o iritare gravă a ochilor. A se păstra departe de surse de căldură, suprafeţe fierbinţi, scântei, flăcări şi alte surse de aprindere. Fumatul interzis. Păstraţi recipientul închis etanş. Purtaţi echipament de protecţie a ochilor/ echipament de protecţie a feţei. ÎN CAZ DE CONTACT CU OCHII: **clătiţi** cu atenţie cu apă timp de mai multe minute. Scoateţi lentilele de contact, dacă este cazul şi dacă acest lucru se poate face cu uşurinţă. Continuaţi să clătiţi. Dacă iritarea ochilor persistă: consultaţi medicul. **Nu amestecati MinutenSpray-classic cu alte substante de curatare sau dezinfectanti sau umplerea in alte sticle de pulverizare.**

Impact asupra mediului:

Substanţele care compun MinutenSpray-classic sunt biodegradabile conform normelor OECD. Pentru a economisi ambalajele şi a reduce impactul asupra mediului, vă recomandăm să folosiţi sistemul de reumplere cubitainer de 5 l.

REF	3002	500 ml flacon cu pulverizator
REF	3003	500 ml flacon cu pulverizator, gol
REF	3006	500 ml flacon
REF	4715	1 l flacon cu pulverizator
REF	3005	5 l canistră

JJJJ-MM

LOT 35xxxx

CE 0123

DesNet +

Dezinfectant de suprafeţe

Lichid concentrat fără aldehide şi fenoli pentru curăţarea şi dezinfectarea eficientă a suprafeţelor dispozitivelor medicale din cabinetele medicale şi stomatologice, cu eficienţă microbiană extinsă.

- **Fără aldehide şi fenoli**

Spectrul de activitate
Bactericid, fungicid şi virucid.

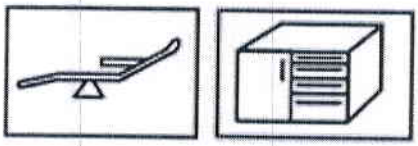
Aplicare:

1. **Igienă generală şi profilaxie**
   0.5 % / 60 minute **sau**
   2.0 % / 15 minute
   => bactericid, fungicid şi virucid impotriva virusilor incapsulati (incl. HBV, HCV, HIV, Herpes simplex, Influenţa incl. H1N1 + H5N1, BVDV, Vaccinia)
2. **Sectoare critice (săli de operaţie)**
   5.0 % / 15 - 30 minute
   => bactericid, fungicid şi virucid impotriva virusilor incapsulati **si** neincapsulati (incl. Adeno, Noro, Polio si Rota)

Compatibilitate ecologică:
Soluţiile de **DesNet +** sunt nedăunătoare mediului înconjurător, ingredienţii (activi + substanţele auxiliare) au fost clasificaţi ca fiind uşor degradabili în conformitate cu testele modificate OECD.

Compoziţie:
5-15 % tenside cationice, tenside nonionice, agenţi de curăţare alcalini, substanţe auxiliare.

Substanţe dezinfectante:
Clorura quaternară de amoniu



Observatii speciale:
Conţine: 2-Aminoetanol (141-43-5), clorură de didecildimetilamoniu (7173-51-5), carbonat de potasiu (584-08-7)

Pericol. Provoacă arsuri grave ale pielii şi lezarea ochilor. Poate provoca iritarea căilor respiratorii. Foarte toxic pentru mediul acvatic. Purtaţi mănuşi de protecţie/îmbrăcăminte de protecţie/ echipament de protecţie a ochilor/ echipament de protecţie a feţei. ÎN CAZ DE ÎNGHIŢIRE: clătiţi gura. NU provocaţi voma. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateţi imediat toată îmbrăcămintea contaminată. Clătiţi pielea cu apă/faceţi duş. ÎN CAZ DE CONTACT CU OCHII: clătiţi cu atenţie cu apă timp de mai multe minute. Scoateţi lentilele de contact, dacă este cazul şi dacă acest lucru se poate face cu uşurinţă. Continuaţi să clătiţi. Sunaţi imediat la un CENTRU DE INFORMARE TOXICOLOGICĂ/un medic. A nu se amesteca cu alţi dezinfectanţi sau detergenţi.

REF 3027 flacon cu dozator de 1 l
REF 3028 canistră de 5 l

JJJJ-MM
LOT 48xxxx
CE 0123

Importator in Moldova, "GBG-MLD"SRL, str.Tighina65, tel:+373542091,+37360999924

BIB forte eco

Concentrat lichid fara aldehide, fenoli si QAC (compusi cuaternari de amoniu) pentru curatarea fara fixarea proteinelor si dezinfectarea instrumentelor medicale/dentare si a instrumentelor rotative de precizie. Are compatibilitate excelenta si cu materialele endoscoapelor.

- Certificare VAH/DGHM

Domeniul de aplicare:
Lichid concentrat foarte eficace pentru aplicarea pe

1.) **instrumentar dental si medical generic** (diagnosticare, profilaxie, chirurgie, precum forcepsuri, elevatoare, oglinzi bucale, endoscoape rigide si flexibile, etc)
2.) **instrumente dentare rotative** din otel normal si extradur, diamantate, freze si bisturie chirurgicale, freze pentru taiat coroane, ace endodontice, gume de lustruit etc.

Spectrul de activitate (la grad mare de incarcare cu proteine):

- **bactericid incl. TBC si MRSA, levurocid (conform EN)**

economic	0.5 %	60 minute
	1.0 %	30 minute
	2.0 %	15 minute
rapid	3.0 %	10 minute in baie ultrasonica
	4.0 %	5 minute in baie ultrasonica

- **inactivarea virusurilor contra virusurilor cu invelis (capsida) incl. HBV, HCV, HIV, Herpes simplex, Influenza (H1N1 + H5N1), BVDV, V- cinia**

0.5 %	60 minute
1.0 %	10 minute

- **inactivarea virusurilor contra virusurilor fara invelis precum Adeno, Noro, Polio conform EN 14476**

3.0%	10 minute in baie ultrasonica (la 55 °C

- **profilaxie CJD (Creutzfeldt-Jakob), corespunde cerintelor RKI (** >=10)

Utilizare:
Recomandam utilizarea **BIB forte eco** la 0.5%. Pentru prepararea solutiei gata-de-utilizat ex. 5 ml concentrat cu 995 ml apa (a se vedea tabelul de dozari). Daca sunt necesari timpi de contact mai redusi, este posibila prepararea unor solutii gata-de-utilizat cu concentratii mai ridicate iar instrumentele pot fi curatate in baie ultrasonica (a se vedea spectrul de activitate).

Pentru curatarea si dezinfectarea instrumentelor, puneti instrumentele in solutia gata-de-utilizat. Dupa expirarea timpului indicat, scoateti instrumentele din solutie si clatiti-le cu apa adecvata (ex. apa deionizata). In cazul unor depuneri persistente curatati cu o perie de plastic sub jetul de apa, dupa care repetati procesul de dezinfectare. Apoi instrumentele trebuiesc sterilizate.

Durata de valabilitate a solutiei gata-de-utilizare:
Solutie gata-de-utilizare (neutilizata) = 30 zile
Solutie gata-de-utilizare (in uz) = 7 zile

Certificari:
Testat pe instrumentele companiei Komet, de asemeni testate si recomandate de: Acurata, Busch & Co., Dentsply Maillefer, Meisinger, VDW, Helmut Zepf.

Date clinice:
Prof. Dr. H.-P. Werner, Schwerin, EN 13624, EN 13727, EN 14561, EN 14562, EN 14563, 2012-09 + 2013-02 • Dr. H. Brill, Hamburg, stabilitate in utilizare, 2012-11; ultra-sunete, 2013-01 • Dr. J. Steinmann, Brema, DVV + EN 14476, 2013-02

Compozitia:
Amines, N-C12-14-alkyltrimethylenedi- (90640-43-0); N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (2372-82-9); 2-Aminoetanol (141-43-5); Guanidine, N,N'''-1,3-propanediylbis-, N-coco alkyl derivatives (98246-84-5); agenti emulsifianti; agenti de complexare; tenside.

Observatii speciale:
Pericol. Lichid şi vapori inflamabili. Nociv în caz de înghiţire. Provoacă arsuri grave ale pielii şi lezarea ochilor. Poate provoca leziuni ale organelor în caz de expunere prelungită sau repetată în caz de înghiţire. Foarte toxic pentru mediul acvatic. Toxic pentru mediul acvatic cu efecte pe termen lung. Conţine piperazina. Risc de reacţie alergică. A se păstra departe de surse de căldură, suprafeţe fierbinţi, scântei, flăcări şi alte surse de aprindere. Fumatul interzis. Purtaţi mănuşi de rotecţie/îmbrăcăminte de protecţie/ echipament de protecţie a ochilor/ echipament de protecţie a feţei. ÎN CAZ DE ÎNGHITIRE: clătiţi gura. NU provocaţi voma. ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateţi imediat toată îmbrăcămintea contaminată. Clătiţi pielea cu apă/faceţi duş. ÎN CAZ DE CONTACT CU OCHII: clătiţi cu atenţie cu apă timp de mai multe minute. Scoateţi lentilele de contact, dacă este cazul şi dacă acest lucru se poate face cu uşurinţă. Continuaţi să clătiţi. Sunaţi imediat la un CENTRU DE INFORMARE TOXICOLOGICĂ /un medic.

REF 3741 sticla cu dozator 1 l
REF 3742 canistra 5 l

JJJJ-MM
LOT 25xxxx

CE 0123

Importator in Moldova, "GBG-MLD"SRL, str.Tighina65, tel:+373542091,+37360999924

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 029056 0067 Rev. 00

Manufacturer:

ALPRO MEDICAL GMBH
Mooswiesenstraße 9
78112 St. Georgen
GERMANY

Facility(ies):

ALPRO MEDICAL GMBH
Mooswiesenstraße 9, 78112 St. Georgen, GERMANY

Product Category(ies):

- **Cleaning and disinfection preparations for water-bearing lines of medical and dental treatment units**
- **Cleaning and disinfection preparations for aspiration and separation systems as well as spittoon bowls of medical and dental treatment units**
- **Disinfection preparations for surfaces of medical products**
- **Preparations for cleaning and disinfection of medical and dental instruments including rotary instruments and endoscopes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713140253

Valid from: 2019-01-18
Valid until: 2023-12-31

Date, 2019-01-18

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequadas são mantidas.
- Auditoria de monitoração realizada regularmente.

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 029056 0069 Rev. 00

Holder of Certificate: **ALPRO MEDICAL GMBH**
Mooswiesenstraße 9
78112 St. Georgen
GERMANY

Facility(ies): ALPRO MEDICAL GMBH
Mooswiesenstraße 9, 78112 St. Georgen, GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Hygiene Agents, Cleaners and Disinfectants for the General Medicine, the Odonthology and Laboratories as well as Special Products for the Water and Waste Water Technique in Medical Treatment Units And Dosage Devices for Decontamination Agents in Medical Devices**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713140812

Valid from: 2019-01-18
Valid until: 2021-12-31

Date, 2019-01-18

Stefan Preiß

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequadas mantidas.
- Auditoria de monitoração realizada regularmente.

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

GUVERNUL REPUBLICII MOLDOVA

28.09.18 Nr A07.PS-01.Rg02-3921

La nr. A07.PS-01.Rg01-1534 din 21.09.2018

GBG-MLD S.R.L.
MD – 2001, or. Chișinău
str. Tighina, 65, of. 607
office@gbg.md

Prin prezenta, Agenția Medicamentului și Dispozitivelor Medicale (în continuare *AMDM*), cu referire la solicitarea Dvs. nr. G-392 din 20.09.2018 cu privire la înregistrarea dispozitivelor medicale în Republica Moldova, Vă comunică următoarele:

Conform Legii nr. 102 din 09 iunie 2017 cu privire la dispozitivele medicale, unica confirmare a faptul că dispozitivele medicale au fost înregistrate este Registrul de Stat al Dispozitivelor Medicale. Registrul este accesibil pe site-ul oficial al AMDM: www.amed.md (Registrul Dispozitivelor Medicale - http://89.32.230.138:8081/).

Totodată, Vă informăm că următoarele dispozitive medicale:

Nr. de înregistrare	***Denumirea dispozitivului medical***	***Denumire comercială***
DM000026511	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	ALPROJET-DD
DM000107528	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	ALPROJET-W
DM000026512	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	DESNET +
DM000026515	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENSPRAY-CLASSIC
DM000026516	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENWIPES
DM000026517	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	MINUTENWIPES JUMBO
DM000026519	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PLASTISEPT ECO
DM000026521	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	PRINTOSEPT-ID
DM000026522	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	BILPRON
DM000026529	DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE	ALPRON
DM000026575	DEZINFECTANT PENTRU CURĂȚAREA INSTRUMENTELOR MEDICALE ȘI CHIRURGICALE	BIB FORTE ECO

de la producătorul *ALPRO MEDICAL GMBH din Germania*, sunt înregistrate și incluse în Registrul de Stat al Dispozitivelor Medicale în baza Ordinului AMDM nr. A07.PS-01.Rg04-229 din 06.11.2017 și A07.PS-01.Rg04-102 din 17.04.2018.

Director general adjunct **Dumitru SAGHIN**

Ex.: Scripcari Adrian
Tel:022 88 43 05
adrian.scripcari@amed.md

Agenția Medicamentului și Dispozitivelor Medicale
Medicines and Medical Devices Agency
Str. Korolenko 2/1, MD-2028, Chișinău, Republica Moldova
Tel: +373 22 884301; e-mail: office@amed.md; web: www.amed.md

G-CERTI Certificate

G-CERTI hereby certifies that

DURICO C&T INC.

33, Oedap 6-gil, Sangju-si, Gyeongsangbuk-do, Korea

Has been audited by G-CERTI and has implemented

Medical Devices-Quality Management Systems

ISO 13485:2003

Scope of Registration

Design, Development, Manufacture and Sevice of Special Paper (Thermal Paper, Ink-Jet Paper, Photographic Paper, Mat Sheet)

Issue Date	**: 30**	**Jun.**	**2017**
Expiry Date	**: 04**	**Jul.**	**2020**
Original Date	**: 05**	**Jul.**	**2014**
Certification No	**: GK - 0233 - MD**		

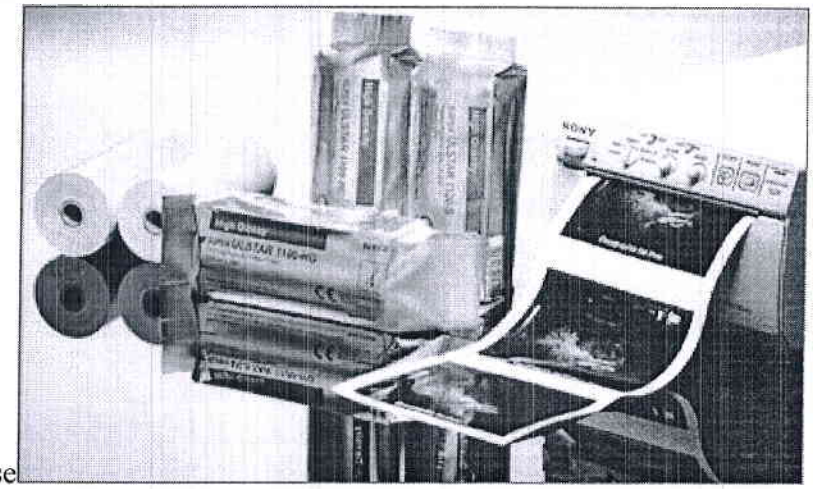
Chief Executive

To verify the validity of this certificate please visit : www.gcerti.com
This is to certify that the Management Systems of this company has been found to confirm to the above G-CERTI FI-12-03

ACCREDITED
Management Systems Certification Body
MSCB-113

G-CERTI SYSTEM SERVICE

Thermal Paper for Video Printers



Medical & Industrial Use

Durico manufactures Synthetic Thermal Papers for printing Ultrasonic Video Images. Durico's Video Papers have become very popular worldwide, **replacing Sony and Mitsubishi papers with Lower Cost and Consistent Quality**. Durico is successfully exporting high image contrast thermal papers to world markets for medical recording and industrial applications.

Superior Quality Medical Image Printing Paper

1. Grades

- **High Glossy Grade – ULSTAR-1100HG**
- **High Density Grade – ULSTAR-1100HD**
- **Standard Grade – ULSTAR-1100S**

2. Applications

- Printing Black & White Video Images on Medical Diagnostic Equipment, such as Ultrasound Systems
- Precision Printing Suitable for Thermal Sensitive Printing Methods

3. Compatibility

- Fitting perfectly to most Sony and Mitsubishi Printers
- Compatible Sony Printers
  - UP-850
  - UP-880
  - UP-870MD
  - UP-890MD
  - UP-895MD
- Compatible Mitsubishi Printers
  - P-70
  - P-90
  - P-91
-

-
- **Paper Equivalents**

DURICO	ULSTAR-1100HG	ULSTAR-1100HD	ULSTAR-1100S
Sony	UPP-110HG	UPP-110HD	UPP-110S
Mitsubishi	K91HG	K65HM	K61S

4. Size

- High Glossy – ULSTAR-1100HG : 110mm x 18m
- High Density – ULSTAR-1100HD : 110mm x 20m
- Standard – ULSTAR-1100S : 110mm x 20m

5. Packing

- Each roll packaged in a pouch
- 5 rolls in an inner box
- 10 inner boxes in a master carton

DNV BUSINESS ASSURANCE

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

Certificate No. 65242-2009-CE-ITA-NA Rev. 2.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

CERACARTA S.P.A.

Italy

for production and final product inspection/testing of

Electromedical Recording Paper

has been assessed with respect to

the conformity assessment procedure described in Article 11.5 and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices for the aspects of manufacture concerned with the conformity of the products with metrological requirements, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 08 September 2014

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
09 September 2019

Angela Lanna
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss, up to but however, such compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 360.000. In this provision "Det Norske Veritas" shall mean the foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
0	Original Certificate	2004-09-09
1	Re-certification	2009-09-09
2	**Re-certification**	**2014-09-09**

Products covered by this Certificate

Product Description	Product	Class
Electromedical Recording Paper	Recording paper for: • ECG • EEG • CTG • laboratory analysis	Im

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

Site Name	Address
CERACARTA S.p.A.	Via Secondo Casadei, 14 - Z.I. Villa Selva – 47122 Forlì, Italy

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

ELITechGroup
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ELITech Clinical Systems SAS
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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 les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(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 standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(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 las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 03 Avril 2015

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

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Cécile GOUBAULT,
Directeur Général
Managing Director
Directora General

ELITech Clinical Systems SAS
Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

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

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
ALBUMIN	ALBU-0600/0700/0250	DOS-CE-ALBU	53597
BILIRUBIN TOTAL 4+1	BITO-0600/0250 BITD-0600	DOS-CE-BILI 4/1	53230
BILIRUBIN DIRECT 4+1	BIDI-0600/0250 BITD-0600		53232
CREATININE JAFFE	CRCO-0600/0700	DOS-CE-CRCO	53251
CREATININE PAP SL	CRSL-0630/0250	DOS-CE-CRSL	53250
IRON TIBC	FECA-0050	DOS-CE-TIBC	53904
GLUCOSE PAP SL	GPSL-0495/0500/0700/ 0507/0707/0250/0455/	DOS-CE-GPSL	53301
GLUCOSE PAP	GLUP-0700	DOS-CE-GLUP	53301
GLUCOSE HK SL	GHSL-0600/0250	DOS-CE-GHSL	53301
HEMOGLOBIN	HEMO-0400/0500	DOS-CE-HEMO	32430
LACTATE	LACT-0100	DOS-CE-LACT	53342
MICROPROTEIN PLUS	PRTU-0600/0250	DOS-CE-PRTU	53481
PHOSPHORUS	PHOS-0600/0230	DOS-CE-PHOS	59123
TOTAL PROTEIN	PRTB-0600/0700/0250	DOS-CE-PRTB	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	DOS-CE-PROB	53985
URIC ACID MONO SL	AUML-0420/0500/0700/ 0427/0507/0707/0250	DOS-CE-AUML	53583
URIC ACID SL	AUSL-0400/0600/0250	DOS-CE-AUSL	53583
URIC ACID	ACUR-0200/0400/0600	DOS-CE-ACUR	53583
UREA UV SL	URSL-0400/0420/0500 0407/0427/0507/0250/0455	DOS-CE-URSL	53587
UREA UV	URUV-0400	DOS-CE-URUV	53587

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 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 les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(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 standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(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 las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 03 Avril 2015

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

Cécile GOUBAULT,
Directeur Général
Managing Director
Directora General

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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-0400/0420/0500/0230	DOS-CE-PASL	52928
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	DOS-CE-ALSL 4+1	52923
ALT /GPT	ALAT-0200/0400	DOS-CE-ALAT	52923
AMYLASE SL	AMSL-0390/0395/0400/0230	DOS-CE-AMSL	52940
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	DC-CE-ASSL 4+1	52954
AST/GOT	ASAT-0200/0400	DOS-CE-ASAT	52954
CHOLINESTERASE	CHES-0053	DOS-CE-CHES	51971
CK NAC SL	CKSL-0410/0430/0230	DOS-CE-CKSL	53003
CK-MB SL	CMSL-0410/0430/0230	DOS-CE-CMSL	52994
CK NAC	CKNA-0030/0200	DOS-CE-CKNA	53003
CK-MB	CKMB-0030	DOS-CE-CKMB	52994
GAMMA-GT SL PLUS	GISL-0400/0420/0500/0250	DOS-CE-GISL	53027
LDH-L SL	LLSL-0400/0420/0230	DOS-CE-LLSL	53072
LDH-P	LDHP-0030	DOS-CE-LDHP	53072

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DCCE-G2 - V22 - Avril /April /Abril 2015

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DECLARATION DE CONFORMITE CE

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

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(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 standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(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 las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 03 Avril 2015

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

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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
CHLORIDE	CHLO-0600/0250	DOS-CE-CHLO	60037
IRON CHROMAZUROL	FECA-0600	DOS-CE-FECA	54758
IRON FERROZINE	FEFR-0600/0250	DOS-CE-FEFR	54758
MAGNESIUM CALMAGITE	MAGN-0600/0125	DOS-CE-MAGN	46795

V. 6 · Cg

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

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DECLARATION DE CONFORMITE CE

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

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(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 standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(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 las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 03 Avril 2015

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

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

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CHOLESTEROL SL	CHSL-0495/0500/0700/ 0507/0707/0250/0455	DOS-CE-CHSL	53359
CHOLESTEROL	CHOL-0220/0420/0720	DOS-CE-CHOL	53359
HDL CHOLESTEROL	HDLC-0060	DOS-CE-HDLC	53391
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	DOS-CE-HDLL	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	DOS-CE-LDLL	53395
TRIGLYCERIDES MONO SL NEW	TGML-425/0495/0515/ 0700/0427/0517/0707	DOS-CE-TGMLN	53460
TRIGLYCERIDES SL	TGML-0250/0455	DOS-CE-TGMLN	53460
TRIGLYCERIDES	TRIG-0200/0400	DOS-CE-TRIG	53460

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DECLARATION DE CONFORMITE CE

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

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(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 standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(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 las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 03 Avril 2015

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
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GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT	44693
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	47869
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT	47869
ISE CONTROL II	ISCT-0047		47869
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
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2	44700
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100	41818
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

V.G. - C.G.

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ELITech Clinical Systems SAS
Société par actions simplifiée au Capital de 1 219 592.14 €
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RC ALENCON 318 365 228

ISO 9001 -NF EN ISO 13485

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

Declaration of conformity

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

Sowińskiego 11 Street
44-101, Gliwice
Poland

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

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliw
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459.9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832.9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823.1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431.1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

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

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

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

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S.R.L. "GBG-MLD" Nr.4

LORNE LABORATORIES LTD.
GREAT BRITAIN

CE

SYPHILIS SEROLOGY KIT
DIRECTIONS FOR USE

RPR CARBON KIT: For Detection Of Syphilis.

SUMMARY

At one time, syphilis was a major medical disease with a host of different manifestations transmitted primarily through sexual contact. The advent of penicillin in 1943 changed this. The etiologic agent of syphilis is *Treponema pallidum*, a spiral bacterium (spirochete). The spirochete causes some damage to the heart and the liver, releasing some tissue fragments. The patient's immune system produces antibodies, called reagins, against these fragments. There are two different techniques for the detection of syphilis. TPHA tests, which detect antibodies to *Treponemal pallidum*, and non-treponemal serologic tests, which detect Reagin in infected people.

PRINCIPLE

When used by the recommended techniques, the reagent will agglutinate (clump) in the presence of reagin. No agglutination usually indicates the absence of reagin (see **Limitations**).

KIT DESCRIPTION

Lorne RPR Carbon Kit is a non-treponemal serologic test for the detection of syphilis. The RPR Carbon Antigen contains micro particulate carbon, which aids in the microscopic reading of results. All the reagents are supplied at optimum dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SPECIMEN COLLECTION

Specimens should be drawn with or without anticoagulant using an aseptic phlebotomy technique. If testing is delayed specimens can be stored at 2-8°C for 7 days or for up to 3 months at or below –20°C. Specimens must be free from bacterial contamination, fibrin, haemolysis and lipaemia.

PRECAUTIONS

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date (see **Vial and Box Labels**).
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. No known tests can guarantee products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.
5. RPR Positive Control: H319 - Causes serious eye irritation. Follow the precautionary statement given in the SDS.

DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES

For information on disposal of kit reagent and decontamination of a spillage site see **Material Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. It is recommended the RPR Positive and Negative Controls be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Shake all the reagents well before use to ensure homogeneity.
3. Do not interchange components between different kits.
4. The circles on the agglutination cards should never be touched with fingers, as this may invalidate the test results.
5. Use of kit and interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of country where reagents are in use.
6. The user must the determine suitability of the kit for use in other techniques.

KIT COMPONENTS PROVIDED

1) RPR Carbon Antigen (Red Label): Carbon particles coated with a lipid complex (cardiolipin, lecithin and cholesterol) in phosphate buffer 20 mmol/L, pH 7.0 containing a preservative.
2) RPR Positive Control (Red cap): Artificial serum with reagin titer ≥ 1/4.
3) RPR Negative Control (Blue cap): Animal serum containing a preservative
4) Dispensing bottle (1 x 2 ml).
5) Dispensing Needle (x1).
6) Disposable agglutination slides.
7) Plastic stirrers.

MATERIALS AND EQUIPMENT NOT SUPPLIED

a) Pipette capable of accurately delivering 50 µl
b) Mechanical rotating table capable of rotating at 80-100 rpm.
c) 9 g/L saline solution.

QUALITATIVE TECHNIQUE

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 50 µL of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the RPR-carbon reagent gently before using. Invert the dropper assembly and press gently to remove air bubbles from the micropipette.
4. Place the micropipette in a vertical position and perpendicular to the slide, and add one drop (20 µL) of this reagent next to the samples to be tested.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample
6. Place the slide on a mechanical rotating table at 80-100 r.p.m. for 8 min. False positive results could appear if the test is read after more than 8 minutes.

INTERPRETATION OF QUALITATIVE RESULTS

1. **Reactive:** Visible agglutination (medium to large clumps) constitutes a positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
2. **Weak-Reactive:** Weak agglutination (small clumps) around the periphery of the test area constitutes a weak positive result and within the accepted limitations of the test procedure, indicates the presence of reagin.
3. **Negative:** No agglutination constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of reagin.

SEMI QUANTITATIVE TECHNIQUE

1. The semi-quantitative test can be performed in the same way as the quantitative technique using dilutions of the serum in 9 g/L saline solution.
2. Make doubling dilutions of specimen as follows:

Dilution	Serum	Saline
1/2	100 µl undiluted serum	100 µl
1/4	100 µl 1/2 diluted serum	100 µl
1/8	100 µl 1/4 diluted serum	100 µl
1/16	100 µl 1/8 diluted serum	100 µl

3. Test the specimen dilutions in the same way as for the quantitative technique above.
4. Read the test and note the last positive dilution series.

STABILITY OF THE REACTIONS

Slide tests should be interpreted straight after the 8-minute rotating period to avoid the possibility that a negative result may be incorrectly interpreted as positive due to drying of the reagent.

LIMITATIONS

1. RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPHA and FTA-Abs to confirm the results.
2. A Non Reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. False positive results have been reported in diseases such as infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases.
4. Bilirubin (≤ 20 mg/dL), hemoglobin (≤ 10 g/L) and lipids (≤ 10 g/L), do not interfere. Rheumatoid factors (≥ 300 IU/mL), interfere. Other substances may interfere[5].
5. False positive or negative results may also occur due to:
   a) Not expelling air from end of needle
   b) Not maintaining dispensing bottle and needle in a vertical position when dispensing the antigen.
   c) When transferring the specimen from the collecting tube some of the specimen being drawn up in to the teat
   d) Contamination of test materials
   e) Improper storage of test materials or omission of reagents
   f) Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne RPR Syphilis Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.
3. The reagent sensitivity is calibrated against the "Human Reactive Serum" from the CDC (Centres for Disease Control) and comparable to the RPR reagent from Becton Dickinson.
4. **Prozone effect:** No prozone effect was detected up to titers ≥1/128.
5. **Diagnostic sensitivity:** 100%
6. **Diagnostic specificity:** 100 %.

DISCLAIMER

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

BIBLIOGRAPHY

1. George P. Schimid. Current Opinion in Infectious Diseases 1994; 7: 34-40.
2. Sandra A Larsen et al. Clinical Microbiology Reviews 1995; 8 (1): 1-21.
3. Sandra Larsen et al. A manual of Test for Syphilis American Public Health Association 1990: 1-192.
4. Joseph Earle Moore et al. Gastrointestinal Haemorrhage 1952; 150(5): 467-473.
5. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.

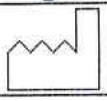
AVAILABLE KIT SIZES

Kit Size	Catalogue Number
150 Tests Per Kit	044150A
500 Tests Per Kit	044500A

For the availability of other sizes, please contact:

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire, RG6 4UT
England
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		

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

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

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

Добровольная сертификация

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17793

Срок действия с 21.06.2016г. **по** 21.06.2019г.

№ 1758739

ОРГАН ПО СЕРТИФИКАЦИИ № RA. RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д.3 тел. (495) 683-97-92, факс (499)187-89-54,
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикаторы бумажные паровой стерилизации многопараметрические химические одноразовые «МедИС-«ВИНАР»
ТУ 9398-027-11764404-2003
Серийный выпуск.

код ОК 005 (ОКП): 93 9854

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

ГОСТ ISO 11140-1-2011 (класс 4),
ГОСТ Р 50444-92 (разделы 3,5,8)

код ТН ВЭД России: 3822 00 000 0

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII ИНН 5023001024
Место производства-141009, Московская обл., г.Мытищи, ул.Колонцова,д.17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д.5, стр.7А, пом.VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-852 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационное удостоверение № РЗН 2013/38 от 08 февраля 2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

ОРГАН ПО СЕРТИФИКАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ Для сертификатов и деклараций М.П. RA.RU.11ИМ02 АНО "ВНИИИМТ"

Руководитель органа _____ Е. И. Полянская
подпись инициалы, фамилия

Эксперт _____ В.В. Русова
подпись инициалы, фамилия

Сертификат не применяется при обязательной сертификации

СИСТЕМА СЕРТИФИКАЦИИ ГОСТ Р

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ РОСС RU.ИМ02.Н17797

Срок действия с 21.06.2016г. по 21.06.2019г.

№ 1758743

ОРГАН ПО СЕРТИФИКАЦИИ № RA.RU.11ИМ02
МЕДИЦИНСКИХ ИЗДЕЛИЙ АНО «ВНИИИМТ»
129301, г. Москва, ул. Касаткина, д. 3 тел. (495) 683-97-92, факс (499)187-89-54
e-mail: im02@bk.ru

ПРОДУКЦИЯ Индикатор бумажный воздушной стерилизации химический многопараметрический одноразовый «МедИС-В-Винар» (модификации МедИС-В-160/150-1, МедИС-В-180/60-1) по ТУ 9398-032-11764404-2004
Серийный выпуск.

код ОК 005 (ОКП): 93 9854

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ НОРМАТИВНЫХ ДОКУМЕНТОВ

код ТН ВЭД России: 3822 00 000 0

ГОСТ ISO 11140-1-2011 (класс 4),

ГОСТ Р 50444-92 (р.р. 3, 5, 8)

ИЗГОТОВИТЕЛЬ Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»), Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII ИНН 5023001024
Место производства - 141009, Московская обл., г. Мытищи, ул. Колонцова, д. 17/2

СЕРТИФИКАТ ВЫДАН Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
Россия, 105094, г. Москва, Госпитальный вал, д. 5, стр. 7А, пом. VIII
тел./факс (495) 988-76-67

НА ОСНОВАНИИ протокола испытаний № 16-854 от 20.06.2016г. ИЦ МИ АНО «ВНИИИМТ» (№ RA.RU.21ИМ04).

Регистрационные удостоверения: № ФСР 2009/04944 от 06.03.2013г., № ФСР 2009/05017 от 06.03.2013г. Федеральной службы по надзору в сфере здравоохранения (РОСЗДРАВНАДЗОР)

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ Маркирование продукции производится знаком соответствия Системы сертификации ГОСТ Р при добровольной сертификации продукции

М.П.

Руководитель органа _____ Е.И. Полянская
подпись инициалы, фамилия

Эксперт _____ В.В. Русова
подпись инициалы, фамилия

Сертификат не применяется при обязательной сертификации

Бланк изготовлен ЗАО "ОПЦИОН", www.opcion.ru, [лицензия № 05-05-09/003 ФНС РФ] тел. (495) 726 4742, г. Москва, 2014 г.

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес:105094, Москва, ул.Госпитальный вал, д.5,стр 7А,пом.VIII
Для писем: 105094, г.Москва, а/я 26
тел/факс: (495) 963-7310, 988-76-67
http://www.vinar.ru e-mail: kolinar@vinar.ru

Исх № 1
от 16.01.13г

Индикаторы бумажные воздушной и паровой стерилизации химические одноразовые серии «МедИС» представляют собой прямоугольные полоски бумажного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полиэфира – 60%.
2. Пигмент – 40%, состоящий:
- оксалат железа 60-90%;
- натриевая соль уксусной кислоты 5-12,5%;
- краситель на основе бромфенолового синего 5-12,5%.

Индикаторы бумажные воздушной и пленочные паровой стерилизации химические одноразовые серии «Стеритест» представляют собой прямоугольные полоски с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:
- нитрат аммония 10-20%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 30-40%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Интест» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 50%.
2. Пигмент – 50%, состоящий:
- нитрат аммония 15-25%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Фарматест» представляют собой прямоугольные полоски бумажно-пленочного

основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:

- щавелевой кислоты 20-40%;
- аммониевой соли щавелевой кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромфенолового синего 10-20%.

Индикаторы паровой стерилизации химические одноразовые «Винар-5класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полиэфирной связки – 72%.
2. Пигмент – 28%, состоящий:

- янтарной кислоты 20-40%;
- натриевой соли янтарной кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы паровой стерилизации химические одноразовые серии «Винар-6 класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полиэфирной связки – 65%.
2. Пигмент – 35%, состоящий:

- карбоновой (щавелевой) кислоты 20-50%;
- калиевой соли щавелевой кислоты 10-40%;
- диоксида титана – 5-20%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы парового обеззараживания химические одноразовые серии «СанИС» представляют собой прямоугольные полоски пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения, с тыльной стороны индикаторы имеют липкий слой, закрытый бумагой.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 55%.
2. Пигмент – 45%, состоящий:

- нитрат аммония 13-20%;
- сульфаминовой кислоты 25-35%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 15-25%.

Генеральный директор
ООО «НПФ «ВИНАР» Андреев В.

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

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBs Ag one Version ULTRA** CODES: **SAG1ULTRA.CE (192 tests)** SAG1ULTRA.CE.96 (96 tests) SAG1ULTRA.CE.480 (480 tests) SAG1ULTRA.CE.960 (960 tests) SAG1ULTRA.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2008 12 0588 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – DECEMBER 2008
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	DIA.PRO. DIAGNOSTIC BIOPROBES s.r.l.

Rev: 12/2013

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.A IDNO 1003600011742 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBs Ab** CODE: **SAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0390 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBc Ab** CODE: **BCAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0391 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

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

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Bio*Pro*bes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBe Ag&Ab** CODE: **HBE.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2004 03 0425 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

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

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HCV Ab** CODES: **CVAB.CE (192 tests)** CVAB.CE.96 (96 tests) CVAB.CE.480 (480 tests) CVAB.CE.960 (960 tests) CVAB.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0392 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO. DIAGNOSTIC BIOPROBES S.r.l.

Rev: 12/2013

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HDV Ab** CODE: **DAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • DESIGN CERTIFICATE N° 2003 12 0393 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

SOCIETATEA CU RASPUNDERE LIMITATA "GBG-MLD" S.R.L. IDNO 1003600117362 REPUBLICA MOLDOVA, MUN. CHIŞINĂU

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

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**Chlamydia Trachomatis IgG** CODE: **CTG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

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

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**CMV IgG** CODE: **CMVG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

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Rev: 12/2013

Dia.Pro
*Dia*gnostic
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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**TOXO IgG** CODE: **TOXOG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
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SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO. DIAGNOSTIC BIOPROBES S.r.l.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" NR.4 IDNO 1003600117562 REPUBLICA MOLDOVA MUR Cahul

Rev:	12/2013

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/EC

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

PRÓRROGA/*EXTENSION* **Fecha inicial/*Inicial date*: 11/12/2003**
Fecha primeraprórroga/ *First extensión date:* 04//12/2008

Certificado Nº/*Certificate Nº*	Fecha de validez/*Date of validity*		ON Nº/ *NB Nº*
2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**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*: *Idem*
Nombre/*Name:*
Dirección/*Address:*

Para los productos/*For the products:*

Categoría/*Category*: *Productos Sanitarios para Diagnóstico in Vitro*/ *In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Inmunología infecciosa / *Infectious immunology*
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 certificados de examen de diseño: **SI**
This certificate must be accompanied by design examination certificate: YES
Este certificado es consecuencia de la auditoria del Sistema Completo de Garantía de Calidad y del examen de la documentación técnica contenida en el expediente Nº 2003 05 0240, y garantiza que los productos descritos cumplen los requisitos de la Directiva.
This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier Nº 2003 05 0240, *and guarantees that the described products fulfils the requirements of the Directive.*

Madrid, 27 de noviembre de 2013

agencia española de
medicamentos y
productos sanitarios
ORGANISMO NOTIFICADO
0318

LA DIRECTORA,
Belén Sánchez Crespo-Eznarriaga

CORREO ELECTRÓNICO
on0318@aemps.es

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
TEL: 902101322
FAX: 91 822 52 89

ANEXO Nº/*ANNEX Nº: I*

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Fecha primera prórroga/ *First extensión date:* **04/12/2008**

Certificado Nº/*Certificate Nº*	Fecha de validez/*Date of validity*		ON Nº/*NB Nº*
2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**0318**

Productos/*Products*:
Productos Sanitarios de Diagnóstico in Vitro. lista A, Anexo II. Directiva 98/79/EC
Nº Productos / *Nº Products*: 18. Nº variantes/ *Nº Variants*: 46

1. Reactivos y productos reactivos para la detección ó confirmación ó cuantificación de marcadores de infección por hepatitis **B** en muestras humanas / *Reagents and reagent products for detection or confimation or quantification, in human specimens, of markers of hepatitis **B** infection*:

1.1. **HBs Ag one.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº /*Described in design certificate Nº* 2003 12 0389 ED).

SAG1.CE (192 tests)
SAG1.CE.96 (96 tests)
SAG1.CE.480 (480 tests)
SAG1.CE.960 (960 tests)

1.2. **HBs Ab.** ELISA cualitativo-cuantitativo/ *qualitative-quantitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2003 12 0390 ED).

SAB.CE (96 tests)

1.3. **HBc Ab.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2003 12 0391 ED)

BCAB.CE (96 tests)

1.4. **HBc IgM.** ELISA cualitativo-cuantitativo/*qualitative-quantitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2004 03 0424 ED)

BCM.CE (96 tests)

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Fecha primera prórroga/ *First extensión date:* 04/12/2008

Certificado Nº/*Certificate Nº*	Fecha de validez/*Date of validity*		ON Nº/*NB Nº*
2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**0318**

1.5. **HBe Ag & Ab.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº */Described in design certificate Nº* 2004 03 0425 ED)

HBE.CE (96 tests)

1.6. **HBs Ag Confirmation.** ELISA para Confirmation */ELISA for confirmation.* (Descrito en el certificado de diseño Nº */Described in design certificate Nº* 2006 11 0511 ED)

SCONF.CE (20 tests)
SCONF.CE.40 (40 tests)

1.7. **HBs Ag one Version ULTRA.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in certificate diseño Nº* 2008 12 0588 ED)

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

1.8. **HBV DNA Quantitation (QT). Real-Time PCR** quantitativo/*quantitative.* (Descrito en el certificado de diseño Nº */Described in design certificate Nº* 2012 09 0790 ED)

HBVDNAQT.CE (50 tests)
HBVDNAQT.CE.25 (25 tests)
HBVDNAQT.CE.100 (100 tests)
HBVDNAQT.CE.150 (150 tests)

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

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Certificado Nº/*Certificate Nº*	Fecha de validez/*Date of validity*		ON Nº/*NB Nº*
2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**0318**

2. Reactivos y productos reactivos para la detección ó confirmación ó cuantificación, de marcadores de infección por hepatitis C, en muestras humanas/ *Reagents and reagent products for detection or confirmation or quantification, in human specimens, of markers of hepatitis C infection.*

2.1. **HCV Ab.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/ *Described in design certificate* Nº 2003 12 0392 ED)

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)

2.2. **HCV Ab Confirmation.** ELISA de confirmación/ *ELISA for confirmation.* (Descrito en el certificado de diseño Nº/*Described in design certificate* Nº 2005 09 0485 ED)

CCONF.CE (12 tests)

2.3. **HCV IgM.** ELISA cualitativo-cuantitativo/ *qualitative-quantitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate* Nº 2007 09 0532 ED)

CVM.CE (96 tests)

3. Reactivos y productos reactivos para la detección ó confirmación ó cuantificación de marcadores de infección por hepatitis **D** en muestras humanas / *Reagent and reagent products for detection or confirmation or quantification, in human specimens, of markers of hepatitis D infection*

3.1. **HDV Ab.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/Described in design certificate Nº 2003 12 0393 ED)

DAB.CE (96 tests)

MINISTERIO DE SANIDAD
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Certificado Nº/*Certificate Nº*	Fecha de validez/*Date of validity*		ON Nº/*NB Nº*
2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**0318**

3.2 **HDV Ag.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2003 12 0394 ED)

DAG.CE (96 tests)

3.3 **HDV IgM.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2003 12 0395 ED)

DIM.CE (96 tests)

3.4 **HDV RNA Quantitation (QT).** Real-Time PCR cuantitativo/*quantitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2009 11 0660 ED)

DRNA.CE (50 tests)
DRNA.CE.25 (25 tests)
DRNA.CE.100 (100 tests)
DRNA.CE.150 (150 tests)

4 Reactivos y productos reactivos para la detección de marcadores de infección por **HTLV I y II,** en muestras humanas/ *Reagents and reagent products for the detection or confirmation and quantification in human specimens of markers of HTLV I and II infection*

4.1 **HTLV I & II Ab.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2005 12 0493 ED)

HTLVAB.CE (192 tests)
HTLVAB.CE.96 (96 tests)
HTLVAB.CE.480 (480 tests)
HTLVAB.CE.960 (960 tests)

MINISTERIO DE SANIDAD
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2003 12 0388 CT	**Desde/*From*: 27/11/2013**	**Hasta/*To* 26/11/2018**	**0318**

4.2 **HTLV I & II Ab Version ULTRA.** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/*Described in design certificate Nº* 2011 11 0775 ED)

HTLVABULTRA.CE (192 tests)
HTLVABULTRA.CE.96 (96 tests)
HTLVABULTRA.CE.480 (480 tests)
HTLVABULTRA.CE. 960 (960 tests)
HTLVABULTRA.CE. DB (192 tests-For Dia. Blood application)

5 Reactivos y productos reactivos para la detección de marcadores de infección por **HIV 1 y 2**, en muestras humanas / *Reagents and reagent products for the detection or confirmation or quantification, in human specimens, of markers of HIV 1 and 2 infection.*

5.1 **HIV Ab & Ag** ELISA cualitativo/*qualitative.* (Descrito en el certificado de diseño Nº/ *Described in certificate de diseño Nº* 2008 02 0539 ED)

IVCOMB.CE (192 tests)
IVCOMB.CE.96 (96 tests)
IVCOMB.CE. 480 (480 tests)
IVCOMB.CE. 960 (960 tests)
IVCOMB.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, 27 de noviembre de 2013

agencia española de medicamentos y productos sanitarios
ORGANISMO NOTIFICADO 0318

LA DIRECTORA,
Belén Crespo Sánchez-Eznarriaga

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD
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