ISO 9001 - NF EN ISO 13485

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 1 «METABOLITES DIVERS », références 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., 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 upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, 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 está documentada por su contenido de cada archivo técnico DOS CE XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

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

SEPPIM S.A.S
Zone Industrielle
61500 SEES - FRANCE

Françoise DEBIAIS,
Président
President
Presidente

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Zone Industrielle - 61500 SEES - France
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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
LACTATE	LACT-0100	DOS-CE-LACT
URIC ACID MONO SL	AUML-0420/0500/0700/ 0427/0507/0707/0250	DOS CE-AUML
URIC ACID SL	AUSL-0400/0600/0250	DOS CE AUSL
URIC ACID	ACUR-0200/0400/0600	DOS CE-ACUR
ALBUMIN	ALBU 0600/0700/0250	DOS-CE-ALBU
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600 BIDI 0600/0250 BITO-0600/0250	DOS CE BILI 4/1
CREATININE JAFFE	CRCO-0600/0700	DOS CE-CRCO
CREATININE PAP SL	CRSL-0630/0250	DOS CE CRSL
IRON TIBC	FECA-0050	DOS-CE-TIBC
GLUCOSE PAP SL	GPSL-0490/0500/0700/ 0507/0707/0250/0455	DOS-CE-GPSL
GLUCOSE PAP	GLUP-0700/0800	DOS-CE-GLUP
GLUCOSE HK SL	GHSL-0600/0250	DOS CE-GHSL
HEMOGLOBIN	HEMO-0400/0500	DOS CE HEMO
MICROPROTEIN	PRTP 0600/0250	DOS CE PRTP
MICROPROTEIN PLUS	PRTU 0600/0250	DOS CE PRTU
PHOSPHORUS	PHOS 0600/0230	DOS CE PHOS
TOTAL PROTEIN	PRTB 0600/0700/0250	DOS CE-PRTB
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	DOS CE PROB
UREA UV SL	URSL 0400/0420/0500 0407/0427/0507/0250/0155	DOS-CE URSL
UREA UV	URUV-0400/0500	DOS CE URUV

SEPPIM S.A.S
Zone Industrielle
61500 SEES - FRANCE

Société par actions simplifiée au Capital de 1 219 502,14 €
SIRET : 378 365 228 00036 APE 2059Z
RCS ALENCON 378 365 228

ISO 9001 - NF EN ISO 13485

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les reactifs 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., 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 upon the contents of each DOS-CE XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, 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 está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

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

Françoise DEBIAIS,
Présidente
President
Presidenta

SEPPIM S.A.S
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61500 SEES - FRANCE
Tél. + 33 (0)2 33 81 21 00

Société par actions simplifiée au Capital de 1 220 000 €
SIRET 318 360 228 00036 - APE 2059Z
RC ALENCON 318 360 228

ISO 9001 - NF EN ISO 13485

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

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
ACID PHOSPHATASE	PACI-0030	DOS-CE-PACI
ALP (DEA) SL	PASL-0400/0420/0500/0230	DOS-CE-PASL
ALP (DEA)	PALC 0030/0200	DOS-CE-PALC
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	DOS-CE-ALSL 4+1
ALT /GPT	ALAT-0200/0400	DOS CE ALAT
AMYLASE SL	AMSL-0300/0395/0400/0230	DOS CE AMSL
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	DC-CE-ASSL 4+1
AST/GOT	ASAT 0200/0400	DOS-CE-ASAT
CHOLINESTERASE	CHES-0053	DOS-CE-CHES
CK NAC SL	CKSL-0410/0430/0230	DOS-CE-CKSL
CK MB SL	CMSL-0410/0430/0230	DOS-CE-CMSL
CK NAC	CKNA 0030/0200	DOS-CE-CKNA
CK MB	CKMB-0030	DOS CE CKMB
GAMMA GT SL	GASL 0400/0420/0500/0250	DOS CE-GASL
GAMMA GT SL PLUS	GISL 0400/0420/0500/0250	DOS-CE-GISL
GAMMA GT	GAGT 0030/0200	DOS CE-GAGT
LDH L SL	LLSL 0400/0420/0230	DOS CE LLSL
LDH P	LDHP 0030	DOS CE LDHP

SEPPIM S.A.S
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61500 SEES - FRANCE
Tél. + 33 (0)2 33 81 21 00

Société par actions simplifiée au Capital de 1 220 000 €
SIRET 318 360 228 00036 - APE 2059Z
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ELITechGroup
SEPPIM

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 13 Septembre 2010

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., 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 upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, September 13th, 2010

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, 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 está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 13 de Septiembre de 2010

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

Françoise DEBIAIS,
Président
President
Presidente

SEPPIM S.A.S.

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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
CALCIUM ARSENAZO	CALA-0600/0250	DOS-CE-CALA
CALCIUM OCPC	CALO-0600	DOS-CE-CALO
CHLORIDE	CHLO-0600/0250	DOS CE CHLO
COPPER	CUIV-0050	DOS-CE-CUIV
IRON CHROMAZUROL	FECA 0600	DOS CE FECA
IRON FERROZINE	FEFR-0600/0250	DOS-CE-FEFR
MAGNESIUM CALMAGITE	MAGN-0600/0125	DOS-CE MAGN

SEPPIM S.A.S.

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., 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 upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, 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 está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

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

Françoise DEBIAIS,
Président
President
Presidente

ISO 9001 - NF EN ISO 13485

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

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
CHOLESTEROL SL	CHSL 0490/0500/0700 0507/0707/0250/0455	DOS CE CHSL
CHOLESTEROL	CHOL-0220/0420/0720	DOS CE CHOL
HDL CHOLESTEROL	HDLC-0060	DOS-CE HDLC
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	DOS-CE HDLL
CHOLESTEROL LDL SL 2G	LDLL-0230/0380	DOS-CE LDLL
TRIGLYCERIDES MONO SL NEW	TGML-0425/0515/0700 0427/0517/0707	DOS-CE-TGMLN
TRIGLYCERIDES SL	TGML-0250/0455	DOS-CE TGMLN
TRIGLYCERIDES	TRIG-0200/0400	DOS CE TRIG

SEPPIM S.A.S

Société par actions simplifiée au Capital de 1 219 592 Euros
SIRET : 318 365 228 00036 - APE 2059Z
RC Alençon 318 365 228

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 10 «PROTEINES SPECIFIQUES », 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 13 Janvier 2011

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 10, "SPECIFIC PROTEINS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to *in vitro* diagnostic medical devices and to the public health code.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, January 13th, 2011

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los dispositivos pertenecientes al grupo 10 : " PROTEÍNAS ESPECÍFICAS ", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico *in vitro* y el código de salud pública.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 13 de Enero de 2011

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

Françoise DEBIAIS,
Président
President
Presidente

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

GROUPE 10 – PROTEINES SPECIFIQUES / GROUP 10 – SPECIFIC PROTEINS
GRUPO 10 - PROTÉINAS ESPECÍFICAS

DESIGNATION DU REACTIF / REAGENT DESIGNATION / DESIGNACIÓN DE REACTIVO	REFERENCES / REFERENCIAS	NOM DU DOSSIER CE / EC FILE NAME / NOMBRE DEL ARCHIVO CE
CRP IP	ICRP-0400	DOS-CE-CRP IP
CRP IP CALIBRATOR H	ICRP 0042	DOS CE CRPCAL
CRP IP CALIBRATOR SET	ICRP-0043	DOS-CE-CRPCAL
CRP IP CONTROL I	ICRP-0046	DOS-CE CRPCON
CRP IP CONTROL II	ICRP-0047	DOS CE CRPCON
APO A1 IP	IAPA-0400	DOS-CE APA
APO B IP	IAPB-0400	DOS CE-APB
APO A1/B IP CALIBRATOR H	IAPO-0042	DOS-CE-APOCalH
APO A1/B IP CONTROL	IAPO-0048	DOS-CE-APOCon
TRANSFERRIN IP	ITRF-0400	DOS CE TRF
PROTEIN IP CALIBRATOR H	IPRO-0041/0042	DOS-CE PROCAL
PROTEIN IP CALIBRATOR SET	IPRO-0043	DOS-CE PROCAL
PROTEIN IP CONTROL	IPRO-0045/0048	DOS-CE PROCON
µALBUMIN IP	IMAL 0400	DOS-CE-MAL
µALBUMIN IP CALIBRATOR H	IMAL-0042	DOS-CE-MALCal
µALBUMIN IP CALIBRATOR SET	IMAL 0043	DOS-CE-MALCal
µALBUMIN IP CONTROL I	IMAL-0046	DOS-CE-MALCon
µALBUMIN IP CONTROL II	IMAL-0047	DOS-CE-MALCon
IgA IP	IIGA 0400	DOS CE-IIGA
IgG IP	IIGG-0400	DOS CE-IIGG
IgM IP	IIGM 0400	DOS CE IIGM
HAPTOGLOBIN IP	IHAP-0400	DOS CE IHAP
OPOSOMUCOID IP	IORO 0400	DOS-CE-IORO
PREALBUMIN IP	IPAL 0400	DOS CE-IPAL
HbA1c	IHBAC 0240	DOS-CE-HBAC
HbA1c CALIBRATOR SET	IHBAC-0043	DOS-CE-HBAC
HbA1c CONTROL L + H	IHBAC 0040	DOS CE HBAC
HbA1c CONTROL 80	IHBAC 0050	DOS CE HBAC80

Société par actions simplifiée au Capital de 1 219 592,14 €
SIRET 318 565 228 00036 APE 2059Z
RCS ALENCON 318 565 228

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ELITechGroup SEPPIM

R É A C T I F S

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

DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les dispositifs appartenant au groupe 12 «SOLUTIONS de LAVAGE POUR EQUIPEMENTS VITAL SCIENTIFIC », 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 s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 10 février 2009

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the devices belonging to Group 12, "CLEANING SOLUTIONS FOR VITAL SCIENTIFIC EQUIPMENT", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to *in vitro* diagnostic medical devices and to the public health code.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, Februray 10th, 2009

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los dispositivos pertenecientes a el grupo 12 : " SOLUCIONES DE LIMPIEZA PARA LOS EQUIPOS VITAL SCIENTIFIC ", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico *in vitro* y el código de salud pública.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX.
(Ver lista adjunta).

Sées, 10 de Febrero de 2009

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

SEPPIM S.A.S.
Zone Industrielle
61500 SEES - FRANCE

Françoise DEBIAIS,
Présidente
President
Presidenta

Société par actions simplifiée au Capital de 1 219 592,14 €
SIRET N° 318 365 228 00036 APE 2059Z
RC ALENCON B 318 365 228

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ELITechGroup SEPPIM

R É A C T I F S

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GROUPE 12 - SOLUTIONS DE LAVAGE POUR EQUIPEMENTS VITAL SCIENTIFIC
GROUP 12 - CLEANING SOLUTIONS FOR VITAL SCIENTIFIC EQUIPMENT
GRUPO 12 –SOLUCIONES DE LIMPIEZA PARA LOS EQUIPOS VITAL SCIENTIFIC

DESIGNATION DU PRODUIT/ PRODUCT DESIGNATION/ DESIGNACIÓN DEL PRODUCTO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
SYSTEM SOLUTION	SLSY-5900	DOS-CE-SOLVS
ACID SOLUTION	SLHC-5900	
SYSTEM CLEANING SOLUTION	SLNA-5900	

Société par actions simplifiée au Capital de 1 219 592,14 €
SIRET N° 318 365 228 00036 APE 2059Z
RC ALENCON B 318 365 228

EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

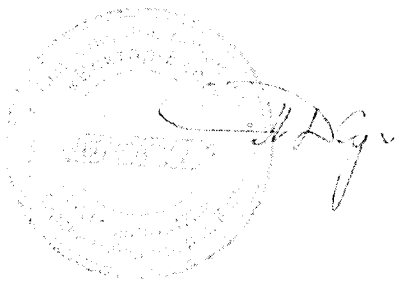
Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

Bioron GmbH
Address: Rheinhorststr. 18, D-67071 Ludwigshafen, Germany, tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2017/10/16



Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the qualitative and quantitative determination of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the quantitative and qualitative determination of IgG to measles virus in blood serum (plasma)	D-1356
3	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to nuclear antigen of Epstein-Barr virus in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to early antigens of Epstein-Barr virus in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	VectoMumps-IgM	Enzyme immunoassay kit for the detection of IgM to mumps virus in blood serum (plasma)	D-2604
11.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
12.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
13.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
14.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
15.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
16	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma)	D-3356
17.	Ascaris-IgG-EIA BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma)	D-3452
18.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgA to tissue transglutaminase in blood serum (plasma)	D-3758
19.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantitative determination of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
20.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 1 concentration in blood serum	D-3762
21.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the determination of pepsinogen 2 concentration in blood serum	D-3764

22.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to Hantavirus in blood serum (plasma)	D-4902
23.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to Hantavirus in blood serum (plasma)	D-4904
24	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile Virus in blood serum (plasma)	D-5150
25.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile Virus in blood serum (plasma)	D-5152
26.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile Virus in blood serum (plasma)	D-5154

Certificate

mdc medical device certification GmbH
certifies that

VECTOR BEST

AO Vector-Best
Research and Production area
building 36, Office 211, Koltsovo
630559 Novosibirsk region
Russian Federation

with the locations listed in the attachment

for the scope

Design and development, production and distribution of medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices -- Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 / ISO 13485:2016

Valid from: 2018-07-13
Valid until: 2021-07-03
Registration no.: D1213100017
Report no.: P18-00489-1179-6
Stuttgart: 2018-07-13

Head of Certification Body

mdc

DAkkS

Attachment of the certificate

No. D1213100017 | date 2018-07-13 | Page 1 of 1

Location	Scope
AO Vector-Best, Arbuzova str, 1/1, 630117 Novosibirsk, Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region, Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best, Pasechnaya str, 3, 630117 Novosibirsk, Russian Federation	design and development, production of medical devices for in vitro diagnostics

mdc

Head of Certification Body

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

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

Product name	Catalogue number
ASO Latex kit	031100A

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

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

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

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

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

Eddy Velthuis
Technical Director

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

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

ООО «МЕДЛАКОР С-П.»
194100, г.С-Петербург, ул.А.Матросова,4,кор.2,Лит.П
Тел./факс (812) 295-87-55, 646-72-23

Утверждаю
Директор
Л.М.Краснопольский

ПАСПОРТ
НАБОР КОНТРОЛЬНЫХ РАСТВОРОВ БЕЛКОВ МОЧИ
«БМ - контроль-ССК»

ТУ 9398-269-52208224-2010 Код ОКП 93 9816
Регистрационное удостоверение № ФСР 2010/08997

Серия № **ПВ 13 - 18**
Годен до **09.2019г.**
Физические показатели в соответствии с техническими условиями

Наименование		Результаты контроля X	X±2S
Серия **ПВ** (для контроля правильности и воспроизводимости)			
1. Концентрация белка, г/л	**Уровень №1**	**0,20**	**(0,16 – 0,24)**
	Уровень №2	**0,40**	**(0,32 - 0,48)**
2. Коэффициент вариации результатов измерения концентрации белков по их реакции с сульфосалициловой кислотой, % , не более		10,0	Соответствует

ЗАКЛЮЧЕНИЕ: соответствует требованиям ТУ

ОТК _____

Дата выдачи 13.11.2018г.

ОТК
принято

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

ПАСПОРТ

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

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

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

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

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

"Агат-Мед"

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

ПАСПОРТ

Набор реагентов для определения
концентрации **белка в моче**, 660 опр. х 3 мл
«Белок в моче - АГАТ».

Серия..... **66/751018** Дата выпуска... **10.2018** Годен до... **11.2020**
Количество наборов в серии... **500**

Наименование показателя	Требования НТД предприятия	Результаты анализа
1. Внешний вид		
1.1 Калибровочный раствор альбумина	Жидкость бесцветная прозрачная без посторонних включений	Жидкость бесцветная прозрачная
1.2 Сульфосалициловая кислота	ГОСТ 4478-78	Соответствует
2. Технические характеристики		
2.1 Значение pH калибровочного раствора альбумина, ед., в интервале	6,5-8,0	Соответствует
3. Показатели правильности определения		
3.1 Соответствие стандартному образцу, отклонение, %, не более	2,0	Соответствует

Заключение ОКК ООО «Агат-Мед»:
Набор серии **66/751018** требованиям НТД предприятия соответствует.

Начальник ОКК ООО «АГАТ-МЕД» Гладун В.В.
«2» октября 2018г.

"Агат-Мед"

МП

GOST R CERTIFICATION SYSTEM
FEDERAL AGENCY FOR TECHNIQUE REGULATION AND METROLOGY

VOLUNTARY CERTIFICATION SYSTEM
"SMK-STANDARD"
Reg. No. РОСС RU.31060.04ЖЖЮ0

Certification authority:
REG No. SMK.STANDART.RU.0005
INTERNATIONAL CERTIFICATION CENTER Limited Liability Company
Address: 138, Naberezhnaya Obvodnogo Canala, block 1, office 421, St. Petersburg, 190020
phone: +7 (812) 438-76-71 standart@iso-smk.ru
Check the authenticity of the certificate in the register on the website http://www.iso-smk.ru

CERTIFICATE OF CONFORMITY

No. ST.RU.0001.M0013380

This Certificate of Conformity is issued to

Agat-Med, Ltd.
Address: 6, Glavnaya st., Moscow, 105173, Russia
TRN 7719187311 OGRN 1037739078970

Date of issue: 26.01.2018 Period of validity: 26.01.2021

This certificate certifies that:

Medical devices. Quality management system. System requirements for regulatory purposes in accordance with Annex 1 to this certificate

(the attachment is an integral part of the certificate.)

CORRESPONDS TO THE REQUIREMENTS OF GOST ISO 13485-2011 (EN ISO 13485:2003)

Manager of "Expert" authority

_____ V.V. Koptsev _____ O.V. Gundareva

THIS CERTIFICATE CONFIRMS THE ORGANIZATION TO MAINTAIN THE ABOVE PERFORMED ACCORDING TO THE STANDARDS ESTABLISHED BY THE INTERNATIONAL BODY OF QUALITY CERTIFICATES
SYSTEM "SMK STANDARD" AND IS CONFIRMED DURING THE ANNUAL CONTROL

GOST R CERTIFICATION SYSTEM
FEDERAL AGENCY FOR TECHNIQUE REGULATION AND METROLOGY
Appendix № 1
to Certificate of Conformity № ST.RU.0001.M0013380
Scope of the quality management system certification:

Relation to the development, manufacture and sale of medical devices for in vitro diagnostic, reagents and kits for clinical biochemistry and calibrators and control materials

Manager of "Expert" authority

_____ V.V. Koptsev _____ O.V. Gundareva

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 28 октября 2013 года № ФСР 2009/04472

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

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

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

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

Номер регистрационного досье № РД-2080/39533 от 23.10.2013

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 2а

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

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

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

0005061

EC Declaration of Conformity for In-vitro-diagnostics

according to directive 98/79/EC

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.

CE

We

Name of manufacturer:	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following reflectometer for professional use

Name of product	**Reference numbers**
URYXXON® 500	930 080

Type:	URINE MULTI-CONSTITUENT TEST STRIPS EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 2013-07-30

Dietmas Czyron

i.A. D. Czyron (QA Manager)

CISQ is a member of

www.iqnet-certification.com

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

ICIM

CERTIFICATO n. 4264/4
CERTIFICATE No.

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

GRUPPO VACUTEST KIMA

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

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

UNI EN ISO 9001:2015

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

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

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

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

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

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

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

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

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

FEDERAZIONE CISQ

www.cisq.com

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

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

GRUPPO VACUTEST KIMA

Head Office and Operative Unit
Via dell'Industria, 12 - I-35020 Arzergrande (PD)
Operative Units
MEUS S.r.l. - Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)
MEUS S.r.l. - Via dell'Industria, 2-16 - I-35020 Arzergrande (PD)
ROLL S.r.l. - Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)
KIMA S.r.l. - Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)
VACUTEST KIMA S.r.l. - Via dell'Industria, 12 - I-35020 Arzergrande (PD)
VACUTEST KIMA S.r.l. - Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

has implemented and maintains a

Quality Management System

for the following scope:

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

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **2019-01-18**
First issued on: **2007-01-18**
Expires on: **2022-01-17**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-103425

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
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IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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ICIM

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

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

GRUPPO VACUTEST KIMA

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

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

UNI CEI EN ISO 13485:2016

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

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

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

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

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

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

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

FEDERAZIONE CISQ
www.cisq.com

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

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

ISO 9001 -NF EN ISO 13485

ELITechGroup
SEPPIM

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 Scientific equipments.

May 22nd, 2012

Noi, subsemnaţii Seppim S.A.S., compania producătoare a reagenţilor 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 Mariller
Zone Industrielle
61500 SEES - FRANCE
Tél. : + 33 (0)2 33 81 21 00 Fax : + 33 (0)2 33 28 77 51
SIRET 318 365 228 00036

intertek
Total Quality. Assured.

CERTIFICATE

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

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

ISO 13485:2016

The quality management system is applicable to:

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

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited
CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

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

MEDICA

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

Products For Health Care

Declaration of Conformity CE

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

Manufacturer

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

Representative

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

Means of Conformity

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

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

Signature:

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

EasyLyte Accessories

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

EasyLyte Accessories, continued

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

MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

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

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of 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 0388 CT	**Desde/*From* 27/11/2018 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 los productos/*For the products:*

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 certificado 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 02405, and guarantees that the described products fulfil the requirements of the Directive.*

Madrid, 26 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios — Localizador: X9GVDEP5C3
Fecha de la firma: 26/11/2018
Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO
on0318@aemps.es

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

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I
CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0388 CT	Desde/*From* 27/11/2018 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*

1. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

1.1. HBs Ag one

- SAG I CE (192 tests)
- SAG I CE 96 (96 tests)
- SAG I CE 480 (480 tests)
- SAG I CE 960 (960 tests)

Descrito en el certificado / *Described in the certificate* 2003 12 0389 ED

1.2. HBs Ab

- SAB CE (96 tests)

Descrito en el certificado / *Described in the certificate* 2003 12 0390 ED

1.3. HBc Ab

- BCAB CE (96 tests)

Descrito en el certificado / *Described in the certificate* 2003 12 0391 ED

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0388 CT	Desde/*From* 27/11/2018 Hasta/*To* 18/11/2023	0318

1.4. HBc IgM

- BCM.CE (96 tests)

Descrito en el certificado / *Described in the certificate* 2004 03 0424 ED

1.5. HBe Ag & Ab

- HBE CE (96 tests)

Descrito en el certificado / *Described in the certificate* 2004 03 0425 ED

1.6. HBs Ag Confirmation

- SCONF CE (20 tests)
- SCONF CE 40 (40 tests)

Descrito en el certificado / *Described in the certificate* 2006 11 0511 ED

1.7. HBs Ag one Version ULTRA

- SAGIULTRA CE (192 tests)
- SAGIULTRA CE 96 (96 tests)
- SAGIULTRA CE 480 (480 tests)
- SAGIULTRA CE 960 (960 tests)
- SAGIULTRA CE DB (192 tests)

Descrito en el certificado / *Described in the certificate* 2008 12 0588 ED

1.8. HCV Ab

- CVAB CE (192 tests)
- CVAB CE 96 (96 tests)
- CVAB CE 480 (480 tests)
- CVAB CE 960 (960 tests)
- CVAB CE DB (192 tests)

Descrito en el certificado / *Described in the certificate* 2003 12 0392 ED

ORGANISMO NOTIFICADO 0318

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2003 12 0388 CT	Desde/*From* 27/11/2018 Hasta/*To* 18/11/2023	0318

1.9. HCV Ab Confirmation

- CCONF.CE (12 tests) — Descrito en el certificado / *Described in the certificate* 2005 09 0485 ED

1.10. HCV IgM

- CVM.CE (96 tests) — Descrito en el certificado / *Described in the certificate* 2007 09 0532 ED

1.11. HCV Ab (Format 20)

- CVAB.CE.FG (192 tests)
- CVAB.CE.FG.96 (96 tests)
- CVAB.CE.FG.480 (480 tests)
- CVAB.CE.FG.960 (960 tests)

Descrito en el certificado / *Described in the certificate* 2015 10 0842 ED

1.12. HDV Ab

- DAB.CE (96 tests) — Descrito en el certificado / *Described in the certificate* 2003 12 0393 ED

1.13. HDV Ag

- DAG.CE (96 tests) — Descrito en el certificado / *Described in the certificate* 2003 12 0394 ED

1.14. HDV IgM

- DIM.CE (96 tests) — Descrito en el certificado / *Described in the certificate* 2003 12 0398 ED

ANEXO Nº/*ANNEX NO:* I
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PRÓRROGA/*EXTENSION* Fecha inicial/ *Initial date:* **11/12/2003**
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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0388 CT	Desde/*From* 27/11/2018 Hasta/*To* 18/11/2023	0318

1.15. HTLV I & II Ab

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

Descrito en el certificado / *Described in the certificate* 2005 12 0493 ED

1.16. HTLV I & II Ab Version ULTRA

- HTLVABULTRA.CE (192 tests)
- HTLVABULTRA.CE.96 (96 tests)
- HTLVABULTRA.CE.480 (480 tests)
- HTLVABULTRA.CE.960 (960 tests)
- HTLVABULTRA.CE.DB (192 tests)

Descrito en el certificado / *Described in the certificate* 2011 11 0775 ED

1.17. HIV Ab & Ag

- IVCOMB.CE (192 tests)
- IVCOMB.CE.96 (96 tests)
- IVCOMB.CE.480 (480 tests)
- IVCOMB.CE.960 (960 tests)
- IVCOMB.CE.DB (192 tests)

Descrito en el certificado / *Described in the certificate* 2008 02 0539 ED

ORGANISMO NOTIFICADO 0318

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0388 CT	**Desde/*From* 27/11/2018 Hasta/*To* 18/11/2023**	**0318**

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR* **[NANDO: IVD 0203]**

2.1. HBV DNA Quantitation (QT)

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

Descrito en el certificado / *Described in the certificate* 2012 09 0790 ED

2.2. HDV RNA Quantitation (QT)

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

Descrito en el certificado / *Described in the certificate* 2009 11 0660 ED

3. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

3.1. DIA.CHEMILUX HCV Ab

- RACVAB.CE (100 tests)

Descrito en el certificado / *Described in the certificate* 2015 01 0834 ED

3.2. DIA.CHEMILUX HBs Ag

- RASAG.CE (100 tests)

Descrito en el certificado / *Described in the certificate* 2015 10 0843 ED

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I
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de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of 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 0388 CT	**Desde/*From* 27/11/2018 Hasta/*To* 18/11/2023**	**0318**

3.3. DIA.CHEMILUX HIV Ab & Ag

- RAIVCOMB.CE (100 tests)

Descrito en el certificado / *Described in the certificate* 2016 02 0844 ED

3.4. DIA.CHEMILUX HBc Ab

- RABCAB.CE (100 tests)

Descrito en el certificado / *Described in the certificate* 2017 07 0863 ED

3.5. DIA.CHEMILUX HTLV I & II Ab

- RAHTLVAB.CE (100 tests)

Descrito en el certificado / *Described in the certificate* 2018 11 0878 ED

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, 26 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

ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

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

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PRÓRROGA/*EXTENSION* — Fecha inicial/ *Initial date:* **10/05/2014**
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 05 0442 CT	**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 los productos/*For the products:*

Categoría/*Category*: Productos Sanitarios para Diagnóstico "In Vitro" */ In Vitro Diagnostic Medical Devices*
Grupo genérico/*Generic group*: Diagnóstico de enfermedades infecciosas */ Diagnostic of infections 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 certificado de examen de diseño: NO
This certificate must be accompanied by design examination certificate: NO

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 02405, and guarantees that 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

ORGANISMO NOTIFICADO 0318

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2004 05 0442 CT	**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 B, anexo II / ***List B, Annex II***

1. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0303; IVD 0305]**

1.1. CMV IgM

- CMVM CE (96 test)

1.2. CMV IgG

- CMVG CE (96 test)

1.3. Toxo IgM

- TOXOM CE (96 tests)

1.4. Toxo IgG

- TOXOG CE (96 tests)

ORGANISMO NOTIFICADO 0318

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
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1.5. RUB IgM

- RUBM CE (96 tests)

1.6. RUB IgG.

- RUBG.CE (96 tests)
- RUBG.CE 192 (192 tests)
- RUBG.CE 480 (480 tests)

1.7. TORCH IgM

- TORCHM CE (96 tests)

1.8. *Chlamydia Trachomatis* IgG

- CTG.CE (96 tests)

1.9. *Chlamydia Trachomatis* IgM

- CTM.CE (96 tests)

1.10. *Chlamydia Trachomatis* IgA

- CTA.CE (96 tests)

1.11. *Chlamydia Pneumoniae* IgG

- CPG.CE (96 tests)

1.12. *Chlamydia Pneumoniae* IgM

- CPM.CE (96 tests)

1.13. *Chlamydia Pneumoniae* IgA

- CPA.CE (96 tests)

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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*
2004 05 0442 CT	Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023	0318

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR)* **[NANDO: IVD 0303; IVD 0305]**

2.1. CMV DNA Quantitation (QT) 2nd Generation

- CMVDNAQT.2G.CE (50 tests)
- CMVDNAQT.2G.CE.25 (25 tests)
- CMVDNAQT.2G.CE.100 (100 tests)
- CMVDNAQT.2G.CE.150 (150 tests)

2.2. Dx CMV Assay

- Dx CMV Assay

2.3. *Toxoplasma Gondii* DNA

- TOXODNA CE (50 tests)
- TOXODNA CE 25 (25 tests)
- TOXODNA CE 100 (100tests)
- TOXODNA CE 150 (150 tests)

2.4. *Chlamydia Trachomatis* DNA

- CTDNA CE (50 tests)
- CTDNA CE 25 (25 tests)
- CTDNA CE.100 (100 tests)
- CTDNA CE.150 (150 tests)

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*
2004 05 0442 CT	Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023	0318

3. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

3.1. DIA.CHEMILUX Cytomegalovirus IgM

- RACMVM.CE (100 tests)

3.2. DIA.CHEMILUX Cytomegalovirus IgG

- RACMVG.CE (100 tests)

3.3. DIA.CHEMILUX Toxoplasma IgM

- RATOXOM.CE (100 tests)

3.4. DIA.CHEMILUX Toxoplasma IgG

- RATOXOG.CE (100 tests)

3.5. DIA.CHEMILUX Rubella IgM

- RARUBM.CE (100 tests)

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Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
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3.6. DIA.CHEMILUX Rubella IgG

- RARUBG.CE (100 tests)

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

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

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

ORGANISMO NOTIFICADO 0318

NovaTec
Immundiagnostica GmbH

Product List – CE Marked

Certified by

ISO 13485:2012

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

2017-11

NovaTec
Immundiagnostica GmbH

NovaLisa® Virology

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

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

NovaLisa ® Bacteriology

Prod. No.	Name
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
CPA0730	Chlamydophila pneumoniae IgA
CPG0730	Chlamydophila pneumoniae IgG
CPM0730	Chlamydophila pneumoniae IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM

MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa ® Parasites

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

NovaLisa ® Worms

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

NovaLisa ® Fungi

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

CANM0060	Candida albicans IgM

NovaLisa ® Hormones

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

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

NovaLine

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

Hormones

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

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

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

Prod. No.	Name
DNOV010	Urinary Cortisol

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

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV22	17 beta-Estradiol Saliva
DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estriol Saliva
DSNOV27	Androstenedione Saliva

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

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

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

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

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

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

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

Prod. No.	Name
DNOV093	CIC-C1q

DNOV094	CIC-C3d
DNOV096	CH-50

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

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

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

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa ® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

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

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

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovaLisa ® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM

HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HSV1G0500	Herpes simples Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
TREG0470	Treponema pallidum
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Quantitative Assays (WHO standardized)

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

NovaLisa ® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG

ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

Antigen Assays

Prod. No.	Name
GIA0160S	Giardia lamblia antigen

NovaLisa ® IgM µ-capture Assays

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

NovaLisa ® Antibody Assays

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

NovaLisa ® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG

AMEA7330	Avidity Measles Virus IgG
ARUR7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa ® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

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

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità / *Validity*

Dal / From: 2019-02-11

Al / To: 2022-02-10

Data emissione / *Issuing Date*
2019-02-11

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* **2012-09-25**

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

T101 14/01

CERTIFICATO
N° Q5 071067 0006 Rev. 00

Titolare del certificato: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Stabilimento(i): Liofilchem S.r.l.
Via Scozia,64026 Roseto degli Abruzzi (TE), ITALIA

Liofilchem S.r.l.
Contrada Piane Vomano,Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Marchio di certificazione:

Campo di applicazione: **Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro**

Norma(e) applicata(e): EN ISO 13485:2016
Dispositivi medici – Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Vedere anche note sul retro.

N° del rapporto: ITA1070742

Valido da: 2018-12-19
Valido fino al: 2021-12-18

Data, 2018-12-19

Stefan Preiß

Pagina 1 di 1
Traduzione per scopi informativi. La sola versione inglese (tedesca) è legalmente impegnativa.

TÜV®

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

Product Service

Certificate
No. Q5 071067 0006 Rev. 00

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Facility(ies): Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Certification Mark:

Scope of Certificate: **Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination. Distribution of other in-vitro diagnostic 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.: ITA1070742

Valid from: 2018-12-19
Valid until: 2021-12-18

Date, 2018-12-19 Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 München • Germany

TÜV®

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 31.0 del 08.01.2016

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic device listed in the attached table, Revision 31.0 of 08.01.2016

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 08.01.2016

Direttore Tecnico Technical Director
Dott. Silvio Brocco

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 31.0 del 08.01.2016

9502	Bacitracin Test 100 Discs
9503	X FACTOR TEST 100 Discs
9504	V FACTOR TEST 100 Discs
9505	V+X FACTOR TEST 100 Discs
9508	METRONIDAZOLE TEST 100 Discs
9511	SULPHONAMIDE TEST 100 Discs
95200	ANAEROBES
95210	ENTEROCOCCI
95220	ENTEROBACTERIA 1
95230	ENTEROBACTERIA URINE
95240	ENTEROBACTERIA 2
95250	PSEUDOMONAS
95260	STAPH
95270	ACINETOBACTER
95280	YEASTS
95290	Strepto
95380	ENTEROBACTERIA
95390	PSEUDOMONAS ACINETOBACTER
95400	ENTEROCOCCI
95410	ANAEROBES
95470	STAPH/STREP
95430	ENTEROBACTERIA URINE
95440	ENTEROBACTERIA FROM URINE AND OTHER SAMPLE
95500	YEASTS
9555	MT HAEMOPHILUS
9562	URINO
9563	MICE
9564	KOS I (Gram + vej) 1 x 100 Test
9565	KOS II Gram - vej 1 x 100 Test
9566	KOS III 100 Test
9567	MULTODISC A
9568	MULTODISC B
9569	MULTODISC C
9570	MULTODISC D
9571	MULTODISC A (100 Pz) (Tender106/2003)
9573	MULTODISC C (100 Pz) (Tender106/2003)
9574	MULTODISC D (100 Pz) (Tender106/2003)
9575	ENTERO RING (Tender238/2006)
9576	PSEUDOMONAS RING (Tender238/2006)
9577	GRAM NEGATIVE RING (Tender238/2006)
9578	GRAM POSITIVE RING (Tender238/2006)
96001	SALMONELLA TYPHI 20 ml
96002	SALMONELLA TYPHI 20 ml
96003	SALMONELLA PARATYPHI AH 20 ml
96004	SALMONELLA PARATYPHI AO 20 ml
96005	SALMONELLA PARATYPHI BH 20 ml
96006	SALMONELLA PARATYPHI BO 20 ml
96007	SALMONELLA TOTALE 20 ml
96008	BRUCELLA ABORTUS 20 ml
96009	SALMONELLA TYPHI TOTALE 20 ml CE
96010	SALMONELLA PARATYPHI A TOTALE 20 ml
96011	PROTEUS OX2 20 ml
96012	PROTEUS OX19 20 ml
96013	PROTEUS OXK 20 ml
96014	FECAL OCCULT BLOOD TEST
96015	FECAL OCCULT BLOOD KIT
96016	[illegible] KIT
96017	SALMONELLA PARATYPHI B TOTALE 20 ml
96018	SALMONELLA PARATYPHI CH 20 ml
96019	SALMONELLA PARATYPHI CO 20 ml
96021	SALMONELLA PARATYPHI C TOTALE 20 ml
96022	BRUCELLA MELITENSIS 20 ml
96023	BRUCELLA SUIS 20 ml
96031	SALMONELLA TYPHI H SLIDE 5 ml
96032	SALMONELLA TYPHI O SLIDE 5 ml
96033	SALMONELLA TYPHI TOTALE 5 ml SLIDE
96034	SALMONELLA PARATYPHI AH SLIDE 5 ml
96035	SALMONELLA PARATYPHI AO 5 ml SLIDE
96036	SALMONELLA PARATYPHI A TOTALE 5ml SLIDE
96037	SALMONELLA PARATYPHI BH 5 ml SLIDE
96038	SALMONELLA PARATYPHI BO 5 ml SLIDE
96039	SALMONELLA PARATYPHI B TOTALE 5ml SLIDE
96040	SALMONELLA PARATYPHI CH 5 ml SLIDE
96041	SALMONELLA PARATYPHI CO 5 ml SLIDE
96042	SALMONELLA PARATYPHI C TOTALE 5 ml SLIDE
96043	BRUCELLA TOTALE SLIDE 5 ml SLIDE
96044	BRUCELLA ABORTUS 5 ml SLIDE
96045	BRUCELLA MELITENSIS SLIDE 5 ml
96046	BRUCELLA BENGAL ROSE SLIDE 5 ml
96047	PROTEUS OX2 5 ml SLIDE
96048	PROTEUS OX19 5 ml SLIDE
96049	PROTEUS OXK 5 ml SLIDE
96093	CONTROLLO NEGATIVO/NEGATIVE CONTROL 0.5ml
96096	POSITIVE CONTROL FOR SALMONELLA 0.5ml
96097	POSITIVE CONTROL FOR PROTEUS 0.5ml
96098	POSITIVE CONTROL FOR BRUCELLA 0.5ml
96142	Legionella Latex Kit
96143	CAMPYLOBACTER LATEX KIT
96144	CLOSTRIDIUM DIFFICILE LATEX KIT
96148	SHIGELLA ANTISERUM
96150	E. COLI O157 LATEX KIT
96151	SALMONELLA LATEX KIT
96153	STREPTO B LATEX KIT
96154	STREPTO A LATEX KIT
96155	BENCE JONES LATEX TEST
96316	Clostridium difficile GDH Card
96317	Clostridium Difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96321	O157 E.coli Card
96401	ONE STEP AMPHETAMINE SCREEN 25 CARDS
96404	ONE STEP COCAINE SCREEN
96405	ONE STEP THC (CANNABIS) SCREEN
96406	ONE STEP METAMPHETAMINE SCREEN 25 CARDS
96411	ONE STEP MORPHINE SCREEN 25 CARDS
96415/26	FECAL OCCULT BLOOD CARD
96418	STREPTO A CARD 10 CARDS
96441	Gonorrhea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
96444	Rapid Kappa Lambda Card
96455	H. PYLORI CARD 10 CARDS
96460	HCG URINE/SERUM CARD 50 CARD
96461	HCG URINE/SERUM CARD 100 CARD
96462	MYCOPLASMA CARD (UNI) 20 Cards
96463	[illegible] CARDS
96464	[illegible] CARDS
96465	[illegible] CARD
96466	[illegible] 20 Cards

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2016 года № ФСР 2012/14183

На медицинское изделие
Набор реагентов для клинического анализа спинномозговой жидкости («ДИАХИМ-ЛИКВОР») по ТУ 9398-056-27428909-2012

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия, 196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Производитель
Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия, 196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Место производства медицинского изделия
192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье **№ РД-9561/60865 от 14.12.2015**

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 22 января 2016 года № 341 [illegible]
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения М.А. Мурашко

0017000

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 22 января 2016 года **№ ФСР 2012/14183**

Лист 1

На медицинское изделие
Набор реагентов для клинического анализа спинномозговой жидкости («ДИАХИМ-ЛИКВОР») по ТУ 9398-056-27428909-2012:
- Реактив Самсона - готов к применению - 1 флакон 30 мл.
- Карболовая кислота - готов к применению - 1 флакон 2,5 г.
- Аммоний сернокислый - готов к применению - 1 флакон (пакет) 85 г.

Руководитель Федеральной службы
по надзору в сфере здравоохранения М.А. Мурашко

Declaration of Conformity

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

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

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

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

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

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 28 Jul 2015

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

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

Appendix

Date: 2012-07-02

List of devices.

Device name	Type/ model/ref number	Risk class	GMDN-code	Date of CE-compliance
RENAMPLASTIN	Thromboplastin rabbit/ IS WHO/BS/95.1796	Low		2012-07-02
APTT-test	Kit for APTT determination/instruction for use Actin-FS	Low		2012-07-02
Fibrinogen-test	Kit for fibrinogen determination/2 IS for Fibrinogen Plasma ver.4 dated 01/04/2008	Low		2012-07-02
Plasma N	Control plasma/Standard Human Plasma Siemens	Low		2012-07-02
Thrombin-reagent	Kit for thrombin time determination/2 IS thrombin human NIBSC code 01/580	Low		2012-07-02
Reachrom AT III	Kit for antithrombin III determination/2 IS Antithrombin Plasma NIBSC code 93/768	Low		2012-07-02

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **Society of persons with hemophilia**

Address: 4 Noviy Zikovsky proyezd, Moscow, Russia,

and

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**
(on product labels printed as:
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

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

- **Hemostasis reagents**

see appendix

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

Title	Document No.	Date of issue
In vitro Diagnostic Medical Devices Directive	98/79/EC	1998-10-27

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

Conformity assessment procedure for CE marking: Medical Device Directive, Annex III

Moscow, Russia; 2012-07-02 ----------

Yury Zhulyov, President, Society of persons with hemophilia

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

Maarn, NL; 2012-07-02 ----------

Olga Teirlinck, Consultant, CEpartner4U BV

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

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department)*: **Society of persons with hemophilia**
Address: 4 Noviy Zikovsky proyezd, Moscow, Russia,

and

2) **European authorized representative: CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

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

- **Hemostasis reagents**

see appendix

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

Title	Document No.	Date of issue
In vitro Diagnostic Medical Devices Directive	98/79/EC	1998-10-27

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

Conformity assessment procedure for CE marking: Medical Device Directive, Annex III

Moscow, Russia; 2012-07-02 ----------

Yury Zhulyov, President, Society of persons with hemophilia

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

Maarn, NL; 2012-07-02 ----------

Olga Teirlinck, Consultant, CEpartner4U BV

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

ООО "Медиклон"

МЕДИКЛОН

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D Супер)

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

Серия: 281411 ОКП: 93 9816

Годен: 11 декабря 2020 г. Объем серии: 10000 мл.

Единица: 100 мл Паспорт: Т-18-11-90 от 19.11.2018

Количество единиц 50

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

Соответствует требованиям ТУ – 9398-101-51203590-2009

ООО "Медиклон"

МЕДИКЛОН

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Наименование: Цоликлон Анти АВ

Серия: 081211 ОКП: 93 9816

Годен: 1 ноября 2020 г. Объем серии: 10000 мл.

Единица: 100 мл Паспорт: Т 18-11-92 от 27.11.2018

Количество единиц 6

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

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

Заведующая лабораторией ООО "Медиклон"

М.С. Сычева

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 31 декабря 2015 года № ФСР 2010/08734

На медицинское изделие
Набор реагентов для исследования фекалий по методу Като («Диахим-КАТО») по ТУ 9398-042-27428909-2010

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия, 196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Производитель
Общество с ограниченной ответственностью "Научно-производственная фирма "АБРИС+" (ООО "НПФ"АБРИС+"), Россия, 196084, Санкт-Петербург, ул. Цветочная, д. 16, лит. М, 2-й этаж

Место производства медицинского изделия
192019, Санкт-Петербург, ул. Профессора Качалова, д. 15а, лит. А

Номер регистрационного досье **№ РД-9559/60784 от 14.12.2015**

Вид медицинского изделия **139290**

Класс потенциального риска применения медицинского изделия 2а

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 31 декабря 2015 года № 10009
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы по надзору в сфере здравоохранения М.А. Мурашко

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007

Настоящее регистрационное удостоверение выдано
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Производитель
Закрытое акционерное общество "Термо Фишер Сайентифик" (ЗАО "Термо Фишер Сайентифик"), Россия, 196240, Санкт-Петербург, ул. Кубинская, д. 73, корп. 1, литер А

Место производства медицинского изделия
196240, Санкт-Петербург, ул. Кубинская, д.73, корп. 1, литер А

Номер регистрационного досье **№ РД-6506/50043 от 04.03.2015**

Вид медицинского изделия -

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

Код Общероссийского классификатора продукции для медицинского изделия **94 4330**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 16 марта 2015 года № 1678
допущено к обращению на территории Российской Федерации.

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

0011726

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 16 марта 2015 года № ФСР 2007/01095

Лист 1

На медицинское изделие
Дозаторы пипеточные, одно- и многоканальные, «Лайт» по ТУ 9443-007-33189998-2007:

1. Дозатор пипеточный ДПОФ-1 -1.
2. Дозатор пипеточный ДПОФ-1-5.
3. Дозатор пипеточный ДПОФ-1-10.
4. Дозатор пипеточный ДПОФ-1-20.
5. Дозатор пипеточный ДПОФ-1 -25.
6. Дозатор пипеточный ДПОФ-1-50.
7. Дозатор пипеточный ДПОФ-1-100.
8. Дозатор пипеточный ДПОФ-1-200.
9. Дозатор пипеточный ДПОФ-1-250.
10. Дозатор пипеточный ДПОФ-1-500.
11. Дозатор пипеточный ДПОФ-1-1000.
12. Дозатор пипеточный ДПОП-1-1-10.
13. Дозатор пипеточный ДПОП-1-2-20.
14. Дозатор пипеточный ДПОП-1-5-50.
15. Дозатор пипеточный ДПОП-1-10-100.
16. Дозатор пипеточный ДПОП-1-20-200.
17. Дозатор пипеточный ДПОП-1-100-1000.
18. Дозатор пипеточный ДПОП-1-1000-10 000.
19. Дозатор пипеточный ДПМП-8-1-10.
20. Дозатор пипеточный ДПМП-8-5-50.
21. Дозатор пипеточный ДПМП-8-30-300.
22. Дозатор пипеточный ДПМП-8-50-300.
23. Дозатор пипеточный ДПМП-12-1-10.
24. Дозатор пипеточный ДПМП-12-5-50.
25. Дозатор пипеточный ДПМП-12-30-300.
26. Дозатор пипеточный ДПМП-12-50-300.
27. Дозатор пипеточный ДПМП-16-5-50.

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