

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

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

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

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages), conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

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

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th, 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

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

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,

Responsable des Affaires Réglementaires

Regulatory Affairs Manager

Responsable de los Asuntos Reglementarios



ELITech Clinical Systems SAS

Zone Industrielle

61500 SEES - France

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

SIRET 318 365 228 00036

Cécile GOUBAULT,

Directeur Général Délégué

Managing Director

Directora General



Société par actions simplifiée au capital de 1.688.392,33 € – SIREN : 318 365 228 – RCS ALENCON

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	
ALBUMIN ENVOY	ALBU-0850	53597
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	
CREATININE PAP SL	CRSL-0630/0250	53250
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPST-0850	
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	53301
GLUCOSE PAP	GPST-M690	
GLUCOSE PAP SL	GPST-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	
PHOSPHORUS ENVOY	PHOS-0850	59123
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	
TOTAL PROTEIN ENVOY	PROB-0850	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	
UREA ENVOY	URSL-0850	53587
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	53583
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	
ALP ENVOY	PIVD-0850	52928
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	52923
AMYLASE	AMSL-M430	
AMYLASE ENVOY	AMSL-0850	52940
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	
AST ENVOY	ASVD-0850	52954
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	
CK NAC SL	CKSL-0410/0430/0230	53003
GAMMA-GT	GISL-M230	
GAMMA-GT PLUS SL	GISL-0400/0420/0250	53027
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	
LDH IFCC	LLSL-M230	53072
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	
LIPASE ENVOY	LPSL-0850	53108
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-éléments / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	
CALCIUM ENVOY	CALA-0850	45789
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	
IRON FERENE	FEFE-0230/0600/M230	54758
MAGNESIUM ENVOY	MAGX-0850	
MAGNESIUM XB	MGXB-0250/0600/M430	46795
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	
CHOLESTEROL ENVOY	CHSL-0850	53359
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	
HDL CHOLESTEROL ENVOY	HDLL-0850	53391
LDL CHOLESTEROL	CLDL-0250/M330	
LDL CHOLESTEROL ENVOY	LDLL-0850	53395
TRIGLYCERIDES	TGML-M690	
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	53460
TRIGLYCERIDES SL	TGML-0250/0455	

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REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.
370 West 1700 South
Logan
Utah
84321
USA

Holds Certificate No:

FM 703046

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

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-05-12

Latest Revision Date: 2021-12-23

Effective Date: 2022-01-11

Expiry Date: 2025-01-10



Page: 1 of 1

...making excellence a habit.™



Dia.Pro
Diagnostic
Bio**Probes**

Letter of Authorization

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

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

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

We, Dia.Pro Diagnostic Bioprobes S.r.l shall supply our distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL with all products in strict compliance with the existing "Distribution Agreement" rev.0121 valid until 31-Dec-2023, with possibility of renewal upon agreement between both parties for an additional period.

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

Sincerely yours,

Date: **Milan, 04-February-2021**

Dia.Pro Diagnostic Bioprobes S.r.l.

DIA. PRO.
DIAGNOSTIC BIOPROBES S.r.l.

Dr.ssa Fiorenza Scozzesi

Legal Representative

DIA.PRO Diagnostic Bioprobes S.r.l.

Sede legale e lab.: Via G. Carducci, 27 – 20099 Sesto S. Giovanni (MI) – Italia

Tel. +39 02 27007161/6450 • Fax +39 02 44386771 • <http://www.diapro.it> • E-mail: info@diapro.it

Capitale sociale €50.000,00 I.V. – P.IVA: 11924660159 – Reg. Imp. 11924660159 – REA 1509959



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E
DEL SERVIZIO FARMACEUTICO

UFFICIO 4 DGDMF –DISPOSITIVI MEDICO DIAGNOSTICI IN VITRO

DGDMF/4/I.5.l.e.2/2022/59

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;

VISTO il D.lgs. n. 332/2000 recante attuazione della direttiva 98/79/CE;

VISTA l'istanza datata 07/04/2022 presentata dalla ditta Dia.Pro Diagnostic BioProbes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;

CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 06 Agosto 2021;

VISTI gli atti d'ufficio;

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical-devices;

HAVING REGARD to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;

HAVING REGARD to the request dated 07/04/2022 submitted by the company Dia.Pro Diagnostic BioProbes Srl located in Via G. Carducci 27 – 20099 Sesto San Giovanni (MI) – C.F. / P.Iva 11924660159;

WHEREAS this company paid the fees required by Ministerial Decree (D.M.) August 6, 2021;

HAVING REGARD to the official deeds;

**SI ATTESTA
IT IS ATTESTED**

che la ditta, Dia.Pro Diagnostic BioProbes Srl con sede legale e sede operativa in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) Italia – C.F./P.Iva 11924660159, è il fabbricante ed ha marcato CE, come dispositivi medico - diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i seguenti prodotti:

that the Company Dia.Pro Diagnostic BioProbes Srl with registered place of business and operative site in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI), Italy – C.F./P.Iva 11924660159, is the manufacturer and affixed CE marking as in vitro diagnostic medical devices, according to the Directive 98/79/EC, to the following products:

LINEA EPATITE / HEPATITIS LINE

PRODOTTO / PRODUCT	CODICE / CODE	TESTS N°
HAV Ab	AVAB.CE	96
HAV IgM	AVM.CE	96
HBc Ab	BCAB.CE	96
HBc IgM	BCM.CE	96

HCV Ab Confirmation	CCONF.CE	12
HCV Ab	CVAB.CE	192
	CVAB.CE.96	96
	CVAB.CE.480	480
	CVAB.CE.960	960
	CVAB.CE.DB	192
HCV IgM	CVM.CE	96
HDV Ab	DAB.CE	96
HDV Ag	DAG.CE	96
HDV IgM	DIM.CE	96
HEV IgG	EVG.CE	96
HEV IgM	EVM.CE	96
HEV Ab Version ULTRA	EVABULTRA.CE	192
	EVABULTRA.CE.96	96
	EVABULTRA.CE.480	480
	EVABULTRA.CE.960	960
HBe Ag&Ab	HBE.CE	96
HBs Ab	SAB.CE	96
HBs Ag one version ULTRA	SAG1ULTRA.CE	192
	SAG1ULTRA.CE.96	96
	SAG1ULTRA.CE.480	480
	SAG1ULTRA.CE.960	960
	SAG1ULTRA.CE.DB	192
HBs Ag Confirmation	SCONF.CE	20
	SCONF.CE.40	40

LINEA RETROVIRUS / RETROVIRUS LINE

PRODOTTO / PRODUCT	CODICE / CODE	TESTS N°
HTLV I&II Ab Version ULTRA	HTLVABULTRA.CE	192
	HTLVABULTRA.CE.96	96
	HTLVABULTRA.CE.480	480
	HTLVABULTRA.CE.960	960
	HTLVABULTRA.CE.DB	192
HIV Ab&Ag	IVCOMB.CE	192
	IVCOMB.CE.96	96
	IVCOMB.CE.480	480
	IVCOMB.CE.960	960
	IVCOMB.CE.DB	192



LINEA TORCH / TORCH LINE

PRODOTTO / PRODUCT	CODICE / CODE	TESTS N°
CMV IgG	CMVG.CE	96
CMV IgM	CMVM.CE	96
HSV1 IgG	HSV1G.CE	96
HSV1 IgM	HSV1M.CE	96
HSV2 IgG	HSV2G.CE	96
HSV2 IgM	HSV2M.CE	96
HSV1&2 IgG	HSVG.CE	96
HSV1&2 IgM	HSV.M.CE	96
RUB IgG	RUBG.CE	96
	RUBG.CE.192	192
	RUBG.CE.480	480
RUB IgM	RUBM.CE	96
TORCH IgM	TORCHM.CE	96
Toxo IgG	TOXOG.CE	96
Toxo IgM	TOXOM.CE	96

LINEA SEROLOGIA / SEROLOGY LINE

PRODOTTO / PRODUCT	CODICE / CODE	TESTS N°
CagA IgA	CAGA.CE	96
CagA IgG	CAGG.CE	96
CoxB IgM	COXBM.CE	96
CoxB IgG	COXBG.CE	96
Chlamydia Pneumoniae IgA	CPA.CE	96
Chlamydia Pneumoniae IgG	CPG.CE	96
Chlamydia Pneumoniae IgM	CPM.CE	96
Chlamydia Trachomatis IgA	CTA.CE	96
Chlamydia Trachomatis IgG	CTG.CE	96
Chlamydia Trachomatis IgM	CTM.CE	96
Dengue virus IgG	DENG.CE	96
Dengue virus IgM	DENM.CE	96
Dengue virus NS1 Ag	DENS1AG.CE	96
Ea IgG	EAG.CE	96
Ea IgM	EAM.CE	96
EBNA IgG	EBNG.CE	96
EBNA IgM	EBNM.CE	96
HP IgA	HPA.CE	96
HP IgG	HPG.CE	96
HP IgM	HPM.CE	96
HP Ag	HPAG.CE	48
	HPAG.CE.96	96
Malaria Ab	MALAB.CE	192
	MALAB.CE.480	480
	MALAB.CE.96	96



	MALAB.CE.960	960
	MALAB.CE.DB	192
Measles virus IgG	MEAG.CE	96
Measles virus IgM	MEAM.CE	96
Meningitis IgG	MENG.CE	96
MTB IgG	MTBG.CE	96
SYPH IgM	SIM.CE	96
Syphilis Ab Version ULTRA	SIABULTRA.CE	192
	SIABULTRA.CE.96	96
	SIABULTRA.CE.480	480
	SIABULTRA.CE.960	960
	SIABULTRA.CE.DB	192
Syphilis Ab One Version ULTRA	SIAB1ULTRA.CE	192
	SIAB1ULTRA.CE.96	96
	SIAB1ULTRA.CE.480	480
	SIAB1ULTRA.CE.960	960
	SIAB1ULTRA.CE.DB	192
T.cruzi Ab	TCAB.CE	192
	TCAB.CE.96	96
	TCAB.CE.480	480
	TCAB.CE.960	960
	TCAB.CE.DB	192
EBV VCA IgA	VCAA.CE	96
VCA IgG	VCAG.CE	96
VCA IgM	VCAM.CE	96
West Nile Virus IgG	WNG.CE	96
West Nile Virus IgM	WNM.CE	96
Parvovirus B19 IgG	PARVOG.CE	96
Parvovirus B19 IgM	PARVOM.CE	96
ZIKV IgM	ZIKVM.CE	96
ZIKV IgG	ZIKVG.CE	96
ZIKV IgG Avidity Test	ZIKVAV.CE	48
CHIKV IgM	CHIKVM.CE	96
CHIKV IgG	CHIKVG.CE	96
TETOX IgG	TETG.CE	96
Yellow Fever Virus IgG	YFVG.CE	96

LINEA AUTOIMMUNITA' / AUTOIMMUNITY LINE

ANA 8 parameters profile	ANA8PRO.CE	12
ANA Screening IgG	ANAS.CE	96
IgG anti Centromere B	CENPB.CE	96
IgG anti dsDNA	DSDNA.CE	96
ENA 6 parameters profile	ENA6PRO.CE	12
ENA Screening IgG	ENAS.CE	96
IgG anti Jo-1	JO1.CE	96
IgG anti U1-snRNP 68	RNP.CE	96
IgG anti Scl-70	SCL70.CE	96



IgC anti Sm	SM.CE	96
IgG anti SSA 52 KD	SSA52.CE	96
IgG anti SSA 60 KD	SSA60.CE	96
IgG anti SSB	SSB.CE	96
Anti Thyroglobulin IgG	TG.CE	96
Anti Thyroid Peroxidase	TPO.CE	96

LINEA COVID-19 / COVID-19 LINE

PRODOTTO / PRODUCT	CODICE / CODE	TESTS N°
COVID-19 IgG	COV19G.CE	96
	COV19G.CE.192	192
COVID-19 IgM	COV19M.CE	96
	COV19M.CE.192	192
COVID-19 IgA	COV19A.CE	96
	COV19A.CE.192	192
COVID-19 Spike 1&2 IgG	COV19GSPIKE.CE	96
	COV19GSPIKE.CE.192	192
ACE2-RBD Neutralization Assay	ACE2-RBDNEUTR.CE	96
COVID-19 IgG Confirmation	COV19CONF.CE	24
COVID-19 IgG/IgM Confirmation and Typing	COV19TY.CE	24

I suddetti prodotti, in base all'art. 4 della direttiva 98/79/CE, sono di libera circolazione e possono essere messi in commercio in Italia e in tutto il territorio dell'Unione Europea.

Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione.

The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.

This certificate is issued on the interested company's request according to the law and for exporting.

IL DIRIGENTE DELL'UFFICIO 4
THE DIRECTOR OF OFFICE 4
(Dott.ssa Antonella Colliardo)

RM/CM

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

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

Certificate Number:

0089217-01

Initial Certification Date:

2019-04-19

Date of Certification Decision:

2022-03-24

Certification Effective Date:

2022-04-18

Certification Expiry Date:

2025-04-18



intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851





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

Product Name:

EasyLyte and accessories per attachment

EasyElectrolyte and accessories per attachment

EasyStat and accessories per attachment

EasyBloodGas and accessories per attachment

Model/Type:


EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH

EasyElectrolyte Na/K/Cl, Na/K/Li

pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct

pH/pCO2/pO2

Manufacturer

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

Representative

 Emergo Europe, Molenstraat 15
NL-2513 BH The Hague, The Netherlands
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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 Reference 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 Maintenance 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

DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

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

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

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

Immunoassay products;

AccuBind® ELISA,

AccuLite® CLIA,

QSure® Control,

Instruments

see appendix

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

<u>Document No.</u>	<u>Title</u>
98/79/EC	<i>In vitro</i> Diagnostic Medical Devices Directive

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

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

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

Lake Forest, USA; 2021-09-20

(Place & date of issue (yyyy-mm-dd))



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

Appendix

Date: 2021-09-20

List of devices.

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Allergy & Anemia							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
Autoimmune							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
Bone Metabolism & Growth							
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
Diabetes							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
Endocrine							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
Fertility & Prenatal							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
Infectious Diseases							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
Neonatal							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
Steroid							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
Thyroid							
Total Triiodothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (fT3) Test System	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triiodothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triiodothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29

Miscellaneous Controls							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16

Miscellaneous Instruments							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analyzer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

Brazil - RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009

Canada - Medical Devices Regulations – Part 1- SOR 98/282

United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,

21 CFR 820 - Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Monobind Inc.

100 North Pointe Drive

Lake Forest, CA 92630

USA

Facility ID: F002818

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4585)

Approved by:
Kevin Mullaney
Director of Certification

Certificate Number: MP19.4585 / Rev 2
Certification Granted: 2019/09/25
Effective Date: 2022/09/25
Expiry Date: 2025/09/24



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412

All valid certifications are listed on NSAI's website – www.nsa-inc.com The continued validity of this certificate may be verified under "Approved Client Listing"



NSAI

Annex to Certificate Number: MP19.4585 / Rev 2

Scope of Registration:

The Design, Manufacture, and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents and Controls. The Distribution of Related Washers and Analyzers.

Activity

Location

Headquarters, Design,
Manufacture

Monobind Inc.
100 North Pointe Drive
Lake Forest, CA 92630
USA
File No.: MP19.4585
Facility ID: F002818

Manufacture, Distribution

Monobind Inc.
103 North Pointe Drive
Lake Forest, CA 92630
USA
File No.: MP19.4585/A
Facility ID: F002818

**Verified by:
Director of Certification**

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

NovaTec Immundiagnostica GmbH

**Waldstraße 23 A6
63128 Dietzenbach
Germany**

for the scope

**immunodiagnostics for the determination of
antibodies against Toxoplasma gondii, Rubella virus,
Cytomegalovirus and Chlamydia
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex IV – excluding Section 4 and 6
of the Council Directive 98/79/EC**

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2018-12-04
Valid until	2023-12-03
Registration no.	D1055500015
Report no.	P18-01143-127558
Stuttgart	2018-10-09



Head of Certification Body



Attachment of the certificate

No. D1055500015

Date 2018-10-09

Page 1 of 1

Product category	Product	Class
immunodiagnostics for the determination of antibodies against Toxoplasma gondii	NovaLisa® Toxoplasma gondii IgA NovaLisa® Toxoplasma gondii IgG NovaLisa® Toxoplasma gondii IgM µ-capture NovaLisa® Avidity Toxoplasma gondii IgG Toxoplasma gondii IgA Toxoplasma gondii IgG Toxoplasma gondii IgM µ-capture Avidity Toxoplasma gondii IgG	List B, Annex II
immunodiagnostics for the determination of antibodies against Rubella virus	NovaLisa® Rubella Virus IgG NovaLisa® Avidity Rubella Virus IgG NovaLisa® Rubella Virus IgM µ-capture Rubella Virus IgG RubellaVirus IgM µ-capture	List B, Annex II
immunodiagnostics for the determination of antibodies against Cytomegalovirus	NovaLisa® Cytomegalovirus (CMV) IgG NovaLisa® Avidity Cytomegalovirus (CMV) IgG NovaLisa® Cytomegalovirus (CMV) IgM Cytomegalovirus (CMV) IgG Cytomegalovirus (CMV) IgM	List B, Annex II
immunodiagnostics for the determination of antibodies against Chlamydia	NovaLisa® Chlamydia pneumoniae IgA NovaLisa® Chlamydia pneumoniae IgG NovaLisa® Chlamydia pneumoniae IgM NovaLisa® Chlamydia trachomatis IgA NovaLisa® Chlamydia trachomatis IgG NovaLisa® Chlamydia trachomatis IgM Novagnost Chlamydia pneumoniae IgA Novagnost Chlamydia pneumoniae IgG Novagnost Chlamydia pneumoniae IgM Novagnost Chlamydia trachomatis IgA Novagnost Chlamydia trachomatis IgG Novagnost Chlamydia trachomatis IgM Chlamydia pneumoniae IgA Chlamydia pneumoniae IgG Chlamydia pneumoniae IgM Chlamydia trachomatis IgA Chlamydia trachomatis IgG Chlamydia trachomatis IgM	List B, Annex II



Head of Certification Body



Certificate

mdc medical device certification GmbH
certifies that



NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

for the scope

**development, manufacturing and distribution of in-vitro diagnostics as well as
installation and service of IVD analyzers for infectious disease diagnostics,
autoimmune diagnostics, tumor diagnostics and for clinical chemistry**

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:2016 - ISO 13485:2016

Valid from	2021-12-04
Valid until	2024-12-03
Registration no.	D1055500017
Report no.	P21-01539-215852
Stuttgart	2021-12-01



Head of Certification Body

