ELITech Clinical Systems
Zone industrielle
61500 Sées - France
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www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

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

Digitally signed by Ceaicovschi Tudor
Date: 2022.02.17 13:12:26 EET
Reason: MoldSign Signature
Location: Moldova

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

Vla

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

ELITECH LATINO AMÉRICA

BIOQUÍMICA

COD.	DESCRIÇÃO	REGISTRO MS
ALBU-0700	ALBUMIN 4 X 250 ml	80171840048
ALBU-0600	ALBUMIN 2 X 125 ml	
PASL-0400	ALP (DEA) SL 2 X 62.5 ml	80171840029
PASL-0420	ALP (DEA) SL 4 X 62.5 ml	
PASL-0500	ALP (DEA) SL 5 X 125 ml	
ALSL-0410	ALT/GPT 4+1 SL 2X62.5 ml	80171840025
ALSL-0430	ALT/GPT 4+1 SL 4X62.5 ml	
ALSL-0510	ALT/GPT 4+1 SL 5X125 ml	
1001410	AMMONIA - R1(a+b): 60ml R2: 8 x 5ml	80171840058
AMSL-0390	AMYLASE SL 1 X 50 ml	80171840038
AMSL-0400	AMYLASE SL 6 X 50 ml	
ASSL-0410	AST/GOT 4+1 SL 2X62.5 ml	80171840039
ASSL-0430	AST/GOT 4+1 SL 4X62.5 ml	
ASSL-0510	AST/GOT 4+1 SL 5X125 ml	
BITD-0600	BILIRUBIN T&D 4+1 2X125 ml	80171840065
BITO-0600	BILIRUBIN T 4+1 2X125 ml	
BIDI-0600	BILIRUBIN D 4+1 2X125 ml	80171840104
CALA-0600	CALCIUM ARSENAZO 2 X 125 ml	80171840050
CHLO-0600	CHLORIDE 2 X 125 ml	80171840044
HDLL-0390	CHOLEST. HDL SL 2G 3X80ml	80171840022
HDLL-0380	CHOLEST. HDL SL 2G 1X80ml	
LDLL-0380	CHOLEST. LDL SL 2G 1X80ml	80171840088
CHSL-0700	CHOLESTEROL SL 4 X 250 ml	80171840026
CHSL-0500	CHOLESTEROL SL 6 X 100 ml	
CKSL-0410	CK NAC SL 2 X 62.5 ml	80171840032
CKSL-0430	CK NAC SL 4 X 62.5 ml	
CMSL-0410	CK-MB SL 2 X 62.5 ml	80171840045
CMSL-0430	CK-MB SL 4 X 62.5 ml	
CRCO-0600	CREATININE JAFFE 2 X 125 ml	80171840028
CRCO-0700	CREATININE JAFFE 4 X 125 ml	
CRSL -0630	CREATININE PAP SL	80171840102
CUIV-0050	COPPER	80171840059
1001158	FRUCTOSAMINE - R1: 19 x 3ml R2: 19 tabletes	80171840070
GASL-0400	GAMMA GT SL 2 X 62.5 ml	80171840034
GASL-0420	GAMMA GT SL 4 X 62.5 ml	
GASL-0500	GAMMA GT SL 5 X 125 ml	
GHSL-0600	GLUCOSE HK 5 X 125 ml	80171840097
GPSL-0700	GLUCOSE PAP SL 4 X 250 ml	80171840049
GPSL-0500	GLUCOSE PAP SL 6 X 100 ml	
FECA-0600	IRON CHROMAZUROL 2 X 125 ml	80171840036
FECA-0050	IRON TIBC 1 X 50 ml 1 X 8 G	80171840091

ELITECH LATINO AMÉRICA

BIOQUÍMICA

COD.	DESCRIÇÃO	REGISTRO MS
LACT-0100	LACTATE 10 X 10 ml	80171840047
LDSL-0410	LDH-P 4+1 SL 2X62.5 ml	80171840046
LDSL-0430	LDH-P 4+1 SL 4X62.5 ml	
1001274	LIPASA - R1: 2 x 10ml + R2 1 x 4ml + STD 1 x 1 ml	80171840067
1001275	LIPASA - R1: 4 x 10ml + R2 1 x 8ml + STD 1 x 1 ml	
MAGN-0600	MAGNESIUM CALMAGITE 2 X 125 ml	80171840035
PRTP-0600	MICROPROTEIN 2X125ml	80171840031
PHOS-0600	PHOSPHORUS 2 X 125 ml	80171840027
10011395	POTASSIUM - R1 (3 x 20 ml) e R2 (3 x 9 ml)	80171840101
1001385	SODIUM - 3 x 20 ml + 3 x 9 ml.	80171840089
PRTB-0600	TOTAL PROTEIN PLUS 2 X 125 ml	80171840043
PRTB-0700	TOTAL PROTEIN PLUS 4 X 250 ml	
TGML-0707	TRIGLICERIDES MONO 4 x 250 ml	80171840053
TGML-0517	TRIGLICERIDES MONO 6 x 100 ml	
TGML-0427	TRIGLICERIDES MONO 6 x 50 ml	
URSL-0400	UREA UV SL 2 X 62.5 ml	80171840037
URSL-0420	UREA UV SL 4 X 62.5 ml	
URSL-0500	UREA UV SL 5 X 125 ml	
AUML-0707	URIC ACID MONO SL 4 x 250 ml	80171840052
AUNL-0507	URIC ACID MONO SL 6 x 100 ml	
AUNL-0427	URIC ACID MONO SL 6 X 50 ml	
1001350	ZINC - R1: 5 x 10ml; R2 1 x 5ml ; R3 10g ; CAL: 1 x 5ml	80171840063

TURBIDIMETRIA

1102154	Alpha1 Ácid Glicoprotein - R1: 1 x 40ml R2: 1 x 10ml	80171840062
1107110	ASO TURBILATEX - R1 Dil: 1 x 40ml; R2 Latex 1 x10ml	80171840072
43070	Cystatin C Turbilatex - R1: 1x 20ml R2: 1 x 4ml	80171840082
HBAC-0240	HbA1c	80171840098
1107140	Turbilatex Ferritin - R1: 1 x 40ml R2 1 x 10 ml CAL 1 x 2 ml	80171840057
1107179	Microalbumin Turbilatex - R1: 1 x 40ml R2: 1 x 10 ml	80171840055
1107105	RF (FR) Turbilatex - R1: 1 x 40ml R2 1 x 10ml RF-CAL: 1 x 2ml	80171840054
1102134	Transferrin - 1 x 40 ml R1. Diluente + 1 x 10 ml R2.	80171840084
43134	CRP-Ultrasensitive (PCR-US)	80171840056
1107101	CRP-Turbilatex(PCR)	80171840105

IMUNOLOGIA

1200102	ASO-Latex - 100 testes: 5ml + 1ml + 1ml; 16 x 6 slides	80171840064
1200101	ASO-Latex - 50 testes: 2,5ml + 1ml + 1ml + 8 x 6 slides	
1200301	CRP-Latex (PCR) - 50 testes: 2,5 ml + 1 ml + 1 ml + 8 x 6 slides	80171840079
1200302	CRP-Latex (PCR) - 100 testes: 5 ml + 1 ml + 1 ml + 16 x 6 slides	
1200202	RF-Latex (FR) - 100 testes: 5ml + 1 x 1ml + 1 x 1ml + 16 x 6 slides	80171840068
1200201	RF-Latex (FR) - 50 testes: 1 x 2.5ml + 1 x 1ml + 1 x 1ml + 8 x 6 slides	
1200502	Waaler Rose - 100 testes: 5ml + 1 ml + 1ml + 16 x 6 slides	80171840078
1200501	Waaler Rose - 50 testes: 2,5ml + 1 ml + 1ml + 8 x 6 slides	

ELITECH LATINO AMÉRICA

SOLUÇÕES

SLNA-5900	SYSTEM CLEANING SOLUTION	80171840051
SLSY-5900	SYSTEM SOLUTION	80171840061
ISRS-0800	ISE Reference Solution	80171840060
ISCC-0280	ISE CLEANER E ISE CONDITONER (Soln B Soln C)	80171840066
SLHC-5900	ACID SOLUTION	80171840069
ISDI-0250	ISE Diluent DIL	80171840071

CONTROLES

1002240	Ammonia/Ethanol Control - STD 4 x 2ml	80171840100
1102115	ASO/CRP/RF CONTROL H - 4 x 1ml	80171840087
1102114	ASO/CRP/RF CONTROL L - 4 X 1 ml	
1007073	Microalbumin Control - Ctl: 1 x 2ml	80171840080
43035	CRP/PCR Ultrasensitive Control - 1 x 2ml	80171840094
1002120	Spintrol H Normal - 4 x 5 ml	80171840076
1002210	Spintrol H Pathologic - 4 x 5 ml	
CKMB-0900	CK-MB CONTROL 4 X 3 ml	80171840030
43076	Cystatin C Control - 2 x 2 ml	80171840073
CONT-0060	ELITROL I 10 X 5 ml	80171840042
CONT-0160	ELITROL II 10 X 5 ml	
1102004	General Proteins Control - 4 x 1 ml	80171840095
HBAC-0049	HbA1c L+H Control	80171840083
1107044	Ferritin Control - Control 1 x 2 ml	80171840090

CALIBRADORES

HDLL-0011	CHOLEST. HDL 2G CALIBR. 1X1 ml	80171840041
43075	Cystatin C Calibrator - CAL 5 x 2ml	80171840093
1102003	General Proteins Calibrator - Cal 1 x 2 ml	80171840086
1002011	SPINTROL H CAL - Cal: 10 x 3 ml	80171840075
1002012	SPINTROL H CAL - Cal: 4 x 3ml	
CALI-0550	ELICAL 2 - 4 X 3 ml	80171840023
ISCA-0250	ISE CALIBRATOR L + H	80171840085
HBAC-0043	HbA1c Calibrator SET	80171840077
LDLL - 0011	CHOLESTEROL LDL 2G CALIBRATOR	80171840081
LDLL - 0041	CHOLESTEROL LDL 2G CALIBRATOR	

EU Declaration of Conformity

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

declares under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of:

- Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *In vitro* diagnostics medical devices ("IVD Regulation")
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS2 Directive"), including Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances ("RoHS3").

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

Catalogue number	Description	GTIN
6004-301	Selectra Mach5	0 3661540 60054 8

Product	**Multiple clinical chemistry analyzer IVD, laboratory, automated**
SRN	**TBD**
Risk Class	**A**
GMDN code	**56676**
Accessories	**See Annex**

Product classification
As per Article 48, section 10 the products are categorized as class A device ("self-declaration").

Conformity assessment procedure
In accordance with:

- Article 18 of the IVD Regulation
- Article 4 of the RoHS2 Directive

Spankeren, January 2021

M.A.S.V.E. Verdaasdonk
Managing Director

EU Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010, AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	UL
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-051:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring.	
	IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
	UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1. General requirements	UL
EMC	IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA

Annex – List of IVD accessories

Catalogue number	Description	GTIN
3201-019	Precision Test Solution	0 3661540 60042 5
6004-338	Drying Block Set	0 3661540 60470 6
6004-351	Cuvette rotor set (3 pieces)	0 3661540 60043 2

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

Clinical Systems

CERTIFICATE

Alexei Legun

has successfully completed the

Selectra Mach5. Make Work Flow

25/05/2021
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

ELITechGroup
EMPOWERING IVD

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The Netherlands
T: +31 313 430 500
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

Spankeren, 16 April 2021

To Whom It May Concern

MANUFACTURER'S AUTHORIZATION LETTER

We, **ELITechGroup B.V.**, manufacturer of automated clinical chemistry analyzers, having factories at:
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

and being a company of the ELITechGroup hereby confirm that:

GBG-MLD SRL
Str. Tighina 65, of. 607
Mun. Chişinău, MD-2001
Moldova

is our distributor in Moldova and is fully authorized to offer and deliver the ELITechGroup B.V. products as mentioned in Appendix A.

GBG-MLD SRL is also authorized in Moldova to:

- register, notify, renew or modify the registration of the products as listed in Appendix A;
- participate in public tenders for supply of automated clinical chemistry analyzers;
- perform service activities.

We guarantee that the quality of our products is corresponding to the requirements for IVD products.

Products will be invoiced via:
ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées
France

This Manufacturer Authorization Letter (MAL) is governed by and construed in accordance with Dutch law and is valid for a period of two (2) years unless terminated with a written notice by the issuer.

ELITechGroup B.V.

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

Maurice Verdaasdonk
Managing Director

CERTIFIED LR ISO 13485

ELITechGroup
EMPOWERING IVD

Appendix A - List of products

- SELECTRA MACH5
  Including all accessories and parts

CERTIFIED ISO 13485

LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

otorga el certificado número

grants the certificate no.

2013 11 0039 EN

según la norma

in accordance with the standard

UNE-EN ISO 13485: 2018

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

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

Medical devices – Quality management systems - Requirements for regulatory purposes

a la empresa

to the company

Dia.Pro Diagnostic Bioprobes S.r.l.

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

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

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

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

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

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

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

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

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

CORREO ELECTRÓNICO
on0318@aemps.es

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

ANEXO I / *ANNEX I*

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

Modificaciones del alcance / *Scope modifications:*

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

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

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

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP Ag** CODE: **HPAG.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES S.r.l.

Rev:	05/2018

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THE INTERNATIONAL CERTIFICATION NETWORK
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.

CERTIFICATO n.
CERTIFICATE No.

4265/5/A

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

MEUS S.r.l.

Unità Operative / *Operative Units*
Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
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 stampi per articoli in plastica per laboratorio analisi.
Via dell'Industria 2-16 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

È 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*

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. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

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. Design and production of moulds for plastic labware.

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.

Il presente certificato è soggetto al rispetto del documento ICIM "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 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	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM 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

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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.

0860CM_03_IT

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ICIM

CERTIFICATO n.
CERTIFICATE No.

4265/5/B

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

ROLL S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È 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*

Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. 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.

Il presente certificato è soggetto al rispetto del documento ICIM "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.

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Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

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CERTIFICATO n.
CERTIFICATE No.

4265/5/D

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

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. 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.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È 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*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. 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.

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. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

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.

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