

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 (6 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 2026).

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons les électrodes conformes à la Directive 2011/65/UE du parlement européen et du conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques incluant la DIRECTIVE DÉLÉGUÉE (UE) 2015/863 DE LA COMMISSION du 31 mars 2015 modifiant l'annexe II de la Directive 2011/65/UE du Parlement européen et du Conseil en ce qui concerne la liste des substances soumises à limitations.

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 (6 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, 2026).

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify electrodes; conform to 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, 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.

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 (6 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 2026).

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos los electrodos conformes con la Directiva 2011/65/UE del parlamento europeo y del consejo del 8 de junio de 2011 sobre restricciones a la utilización de algunas sustancias peligrosas en aparatos eléctricos y electrónicos incluyendo la Directiva delegada (UE) 2015/863 de la comisión del 31 de marzo de 2015 por la que se modifica el anexo II de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo en cuanto a la lista de sustancias restringidas.

Sées, le 12 octobre 2023

Valérie LAMBERT,

Responsable des Affaires Réglementaires

Regulatory Affairs Manager

Responsable de los Asuntos Reglamentarios



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Cécile GOUBAULT,

Directeur Général-Délégué

Managing Director

Directora General



Annex

REF	PRODUCT NAME	GMDN Code
3918-004	Sodium Electrode (Na+)	52896
3918-005	Potassium Electrode (K+)	52892
3918-006	Chloride Electrode (Cl-)	52876
3918-003	Carbon Dioxide Electrode (CO2)	60773
3918-002	Reference Electrode (REF)	59241
ALBU-0250	ALBUMIN	53597
ALBU-5220	ALBUMIN	53597
ALBU-0600	ALBUMIN	53597
ALBU-5600	ALBUMIN	53597
ALBU-0700	ALBUMIN	53597
ALBU-5700	ALBUMIN	53597
ALBU-M830	ALBUMIN	53597
ALBU-5M30	ALBUMIN	53597
ALPI-0230	ALP IFCC	52928
ALPI-5100	ALP IFCC	52928
ALPI-6050	ALP IFCC	52928
ALSL-0250	ALT/GPT 4+1 SL	52923
ALSL-5220	ALT/GPT 4+1 SL	52923
ALSL-6050	ALT/GPT 4+1 SL	52923
ALSL-0410	ALT/GPT 4+1 SL	52923
ALSL-5415	ALT/GPT 4+1 SL	52923
ALSL-6255	ALT/GPT 4+1 SL	52923
ALSL-0430	ALT/GPT 4+1 SL	52923
ALSL-0455	ALT/GPT 4+1 SL	52923
ALSL-0510	ALT/GPT 4+1 SL	52923
ALSL-5515	ALT/GPT 4+1 SL	52923
ALSL-6615	ALT/GPT 4+1 SL	52923
ALSL-M490	ALT/GPT	52923
ALSL-5M90	ALT/GPT	52923
ALSL-6M30	ALT/GPT	52923
AMSL-0230	AMYLASE SL	52940
AMSL-5220	AMYLASE SL	52940
AMSL-0390	AMYLASE SL	52940
AMSL-5405	AMYLASE SL	52940
AMSL-0400	AMYLASE SL	52940
AMSL-M430	AMYLASE	52940
AMSL-5M30	AMYLASE	52940
ASLO-0250	ANTI-STREPTOLYSIN O	59055
ASLO-5025	ANTI-STREPTOLYSIN O	59055
ASLO-6006	ANTI-STREPTOLYSIN O	59055
ASLO-4001	ANTI-STREPTOLYSIN O	51744
ASSL-0250	AST/GOT 4+1 SL	52954
ASSL-5220	AST/GOT 4+1 SL	52954
ASSL-6050	AST/GOT 4+1 SL	52954
ASSL-0410	AST/GOT 4+1 SL	52954
ASSL-5415	AST/GOT 4+1 SL	52954
ASSL-6255	AST/GOT 4+1 SL	52954
ASSL-0430	AST/GOT 4+1 SL	52954
ASSL-0455	AST/GOT 4+1 SL	52954
ASSL-0510	AST/GOT 4+1 SL	52954
ASSL-5515	AST/GOT 4+1 SL	52954
ASSL-6615	AST/GOT 4+1 SL	52954
ASSL-M490	AST/GOT	52954
ASSL-5M90	AST/GOT	52954
ASSL-6M30	AST/GOT	52954
AUML-0250	URIC ACID MONO SL	53583
AUML-5220	URIC ACID MONO SL	53583
AUML-0420	URIC ACID MONO SL	53583
AUML-5405	URIC ACID MONO SL	53583
AUML-0427	URIC ACID MONO SL	53583
AUML-0497	URIC ACID MONO SL	53583
AUML-5505	URIC ACID MONO SL	53583
AUML-0500	URIC ACID MONO SL	53583
AUML-0507	URIC ACID MONO SL	53583
AUML-0707	URIC ACID MONO SL	53583
AUML-5710	URIC ACID MONO SL	53583
AUML-M830	URIC ACID	53583
AUML-5M30	URIC ACID	53583
AUSL-0250	URIC ACID SL	53583
AUSL-5220	URIC ACID SL	53583
AUSL-6050	URIC ACID SL	53583
BIDI-0250	BILIRUBIN DIRECT 4+1	53233
BIDI-5220	BILIRUBIN DIRECT 4+1	53233
BIDI-6050	BILIRUBIN DIRECT 4+1	53233
BIDI-0500	BILIRUBIN DIRECT	53233
BIDI-5600	BILIRUBIN DIRECT	53233
BITD-6250	BILIRUBIN DIRECT	53233

Annex

REF	PRODUCT NAME	GMDN Code
BIDI-M430	DIRECT BILIRUBIN	53233
BIDI-5M30	DIRECT BILIRUBIN	53233
BIDI-6M10	DIRECT BILIRUBIN	53233
BIDV-0850	DIRECT BILIRUBIN ENVOY	53233
BITO-0250	BILIRUBIN TOTAL 4+1	53229
BITO-5220	BILIRUBIN TOTAL 4+1	53229
BITO-6050	BILIRUBIN TOTAL 4+1	53229
BITO-0600	BILIRUBIN TOTAL 4+1	53229
BITO-5600	BILIRUBIN TOTAL 4+1	53229
BITD-6400	BILIRUBIN TOTAL 4+1	53229
BITO-M430	TOTAL BILIRUBIN	53229
BITO-5M30	TOTAL BILIRUBIN	53229
BITO-6M10	TOTAL BILIRUBIN	53229
BITV-0850	TOTAL BILIRUBIN ENVOY	53229
CALA-0250	CALCIUM ARSENAZO	45789
CALA-5220	CALCIUM ARSENAZO	45789
CALA-0600	CALCIUM ARSENAZO	45789
CALA-5600	CALCIUM ARSENAZO	45789
CALA-M430	CALCIUM ARSENAZO	45789
CALA-5M30	CALCIUM ARSENAZO	45789
CALI-0550	ELICAL 2	47868
CALI-1550	ELICAL 2	47868
CHDL-0250	HDL CHOLESTEROL	53391
CHDL-5021	HDL CHOLESTEROL	53391
CHDL-6014	HDL CHOLESTEROL	53391
CHDL-0600	HDL CHOLESTEROL	53391
CHDL-5090	HDL CHOLESTEROL	53391
CHDL-6060	HDL CHOLESTEROL	53391
CHDL-M330	HDL CHOLESTEROL	53391
CHDL-5M30	HDL CHOLESTEROL	53391
CHDL-6M30	HDL CHOLESTEROL	53391
CHEB-0250	CHOLINESTERASE	52971
CHEB-5008	CHOLINESTERASE	52971
CHEB-6005	CHOLINESTERASE	52971
CHSL-0250	CHOLESTEROL SL	53359
CHSL-5220	CHOLESTEROL SL	53359
CHSL-0455	CHOLESTEROL SL	53359
CHSL-0497	CHOLESTEROL SL	53359
CHSL-5505	CHOLESTEROL SL	53359
CHSL-0500	CHOLESTEROL SL	53359
CHSL-0507	CHOLESTEROL SL	53359
CHSL-0700	CHOLESTEROL SL	53359
CHSL-5710	CHOLESTEROL SL	53359
CHSL-0707	CHOLESTEROL SL	53359
CHSL-M690	CHOLESTEROL	53359
CHSL-5M90	CHOLESTEROL	53359
CKMB-0900	CK-MB CONTROL	44693
CKMB-1030	CK-MB CONTROL	44693
CKSL-0230	CK NAC SL	53003
CKSL-5220	CK NAC SL	53003
CKSL-6050	CK NAC SL	53003
CKSL-0410	CK NAC SL	53003
CKSL-5405	CK NAC SL	53003
CKSL-6255	CK NAC SL	53003
CKSL-0430	CK NAC SL	53003
CKSL-M230	CK NAC	53003
CKSL-5M30	CK NAC	53003
CKSL-6M10	CK NAC	53003
CLDL-0250	LDL CHOLESTEROL	53395
CLDL-5021	LDL CHOLESTEROL	53395
CLDL-6014	LDL CHOLESTEROL	53395
CLDL-M330	LDL CHOLESTEROL	53395
CLDL-5M30	LDL CHOLESTEROL	53395
CLDL-6M30	LDL CHOLESTEROL	53395
CMSL-0230	CK-MB	52994
CMSL-5220	CK-MB	52994
CMSL-6220	CK-MB	52994
CMSL-WR	CK-MB	52994
CMSL-0410	CK-MB SL	52994
CMSL-5405	CK-MB SL	52994
CMSL-6255	CK-MB SL	52994
CONT-0060	ELITROL I	47869
CONT-1060	ELITROL I	47869
CONT-0160	ELITROL II	47869
CONT-1160	ELITROL II	47869
CRCO-0600	CREATININE JAFFE	53251
CRCO-5600	CREATININE JAFFE	53251
CRCO-6600	CREATININE JAFFE	53251
CRCO-0700	CREATININE JAFFE	53251

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Annex

REF	PRODUCT NAME	GMDN Code
CRSL-0250	CREATININE PAP SL	53250
CRSL-5221	CREATININE PAP SL	53250
CRSL-6070	CREATININE PAP SL	53250
CRSL-0630	CREATININE PAP SL	53250
CRSL-5505	CREATININE PAP SL	53250
CRSL-6470	CREATININE PAP SL	53250
CRSL-M490	CREATININE PAP	53250
CRSL-5M90	CREATININE PAP	53250
CRSL-6M30	CREATININE PAP	53250
FEFE-0230	IRON FERENE	54758
FEFE-5140	IRON FERENE	54758
FEFE-6040	IRON FERENE	54758
FEFE-0600	IRON FERENE	54758
FEFE-5600	IRON FERENE	54758
FEFE-6400	IRON FERENE	54758
FEFE-0850	IRON ENVOY	54758
FEFE-M230	IRON FERENE	54758
FEFE-5M30	IRON FERENE	54758
FEFE-6M10	IRON FERENE	54758
GHSL-0250	GLUCOSE HK SL	53301
GHSL-5220	GLUCOSE HK SL	53301
GHSL-6050	GLUCOSE HK SL	53301
GHSL-0600	GLUCOSE HK SL	53301
GHSL-5505	GLUCOSE HK SL	53301
GHSL-6605	GLUCOSE HK SL	53301
GHSL-M490	GLUCOSE HK	53301
GHSL-5M90	GLUCOSE HK	53301
GHSL-6M30	GLUCOSE HK	53301
GISL-0250	GAMMA-GT PLUS SL	53027
GISL-5220	GAMMA-GT PLUS SL	53027
GISL-6050	GAMMA-GT PLUS SL	53027
GISL-0400	GAMMA-GT PLUS SL	53027
GISL-0420	GAMMA-GT PLUS SL	53027
GISL-5405	GAMMA-GT PLUS SL	53027
GISL-6255	GAMMA-GT PLUS SL	53027
GISL-M230	GAMMA-GT	53027
GISL-5M30	GAMMA-GT	53027
GISL-6M10	GAMMA-GT	53027
GPSL-0250	GLUCOSE PAP SL	53301
GPSL-5220	GLUCOSE PAP SL	53301
GPSL-0455	GLUCOSE PAP SL	53301
GPSL-0497	GLUCOSE PAP SL	53301
GPSL-5505	GLUCOSE PAP SL	53301
GPSL-0500	GLUCOSE PAP SL	53301
GPSL-0507	GLUCOSE PAP SL	53301
GPSL-0700	GLUCOSE PAP SL	53301
GPSL-5710	GLUCOSE PAP SL	53301
GPSL-0707	GLUCOSE PAP SL	53301
GPSL-M690	GLUCOSE PAP	53301
GPSL-5M90	GLUCOSE PAP	53301
HBAC-0043	HbA1c CALIBRATOR SET	53315
HBAC-4301	HbA1c CALIBRATOR SET	53315
HBAC-4302	HbA1c CALIBRATOR SET	53315
HBAC-4303	HbA1c CALIBRATOR SET	53315
HBAC-4304	HbA1c CALIBRATOR SET	53315
HBAC-0049	HbA1c CONTROL L + H	44435
HBAC-4605	HbA1c CONTROL L + H	44435
HBAC-4705	HbA1c CONTROL L + H	44435
HBAC-0240	HbA1c	59090
HBAC-5224	HbA1c	59090
HBAC-6076	HbA1c	59090
HBAC-6004	HbA1c	59090
HBAC-7225	HbA1c	59090
HBAE-0043	HbA1c Enzymatic Calibrator Set	53315
HBAE-4301	HbA1c Enzymatic Calibrator Set	53315
HBAE-4303	HbA1c Enzymatic Calibrator Set	53315
HBAE-M130	HbA1c Enzymatic	63151
HBAE-5M30	HbA1c Enzymatic	63151
HBAE-6M30	HbA1c Enzymatic	63151
HBAE-7050	HbA1c Enzymatic	63151
HDLL-0011	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0041	CHOLESTEROL HDL 2G CALIBRATOR	44696
HDLL-0230	CHOLESTEROL HDL SL 2G	53391
HDLL-0380	CHOLESTEROL HDL SL 2G	53391
HDLL-0390	CHOLESTEROL HDL SL 2G	53391
HLCA-0041	HDL LDL CALIBRATOR	47868
HLCA-4001	HDL LDL CALIBRATOR	47868
ICRP-0043	CRP IP CALIBRATOR SET	41838

Annex

REF	PRODUCT NAME	GMDN Code
ICRP-4311	CRP IP CALIBRATOR SET	41838
ICRP-4312	CRP IP CALIBRATOR SET	41838
ICRP-4313	CRP IP CALIBRATOR SET	41838
ICRP-4314	CRP IP CALIBRATOR SET	41838
ICRP-4315	CRP IP CALIBRATOR SET	41838
ICRP-0046	CRP IP CONTROL I	41839
ICRP-4610	CRP IP CONTROL I	41839
ICRP-0047	CRP IP CONTROL II	41839
ICRP-4710	CRP IP CONTROL II	41839
ICRP-0400	CRP IP	53705
ICRP-6125	CRP IP	53705
ICRP-5025	CRP IP	53705
ICRP-M230	CRP IP	53705
ICRP-6M30	CRP IP	53705
ICRP-5M30	CRP IP	53705
IFRT-0042	FERRITIN CALIBRATOR	41927
IFRT-4230	FERRITIN CALIBRATOR	41927
IFRT-0230	FERRITIN	53718
IFRT-5020	FERRITIN	53718
IFRT-6005	FERRITIN	53718
IHAP-0400	HAPTOGLOBIN IP	53737
IHAP-6125	HAPTOGLOBIN IP	53737
IHAP-5025	HAPTOGLOBIN IP	53737
IIGA-0400	IgA IP	53760
IIGA-6125	IgA IP	53760
IIGA-5025	IgA IP	53760
IIGG-0400	IgG IP	53787
IIGG-6125	IgG IP	53787
IIGG-5025	IgG IP	53787
IIGM-0400	IgM IP	53795
IIGM-6125	IgM IP	53795
IIGM-5025	IgM IP	53795
IMAL-0043	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4311	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4312	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4313	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4314	µALBUMIN IP CALIBRATOR SET	53477
IMAL-4315	µALBUMIN IP CALIBRATOR SET	53477
IMAL-0046	µALBUMIN IP CONTROL I	53478
IMAL-4610	µALBUMIN IP CONTROL I	53478
IMAL-0047	µALBUMIN IP CONTROL II	53478
IMAL-4710	µALBUMIN IP CONTROL II	53478
IMAL-0400	µALBUMIN IP	53475
IMAL-6125	µALBUMIN IP	53475
IMAL-5025	µALBUMIN IP	53475
IMAL-M230	MICROALBUMIN IP	53475
IMAL-6M30	MICROALBUMIN IP	53475
IMAL-5M30	MICROALBUMIN IP	53475
IORO-0400	OROSOMUCOID IP	53606
IORO-6125	OROSOMUCOID IP	53606
IORO-5025	OROSOMUCOID IP	53606
IPAL-0400	PREALBUMIN IP	53957
IPAL-6125	PREALBUMIN IP	53957
IPAL-5025	PREALBUMIN IP	53957
IPRO-0043	PROTEIN IP CALIBRATOR SET	53593
IPRO-4311	PROTEIN IP CALIBRATOR SET	53593
IPRO-4312	PROTEIN IP CALIBRATOR SET	53593
IPRO-4313	PROTEIN IP CALIBRATOR SET	53593
IPRO-4314	PROTEIN IP CALIBRATOR SET	53593
IPRO-4315	PROTEIN IP CALIBRATOR SET	53593
IRCT-0046	RHEUMATOLOGY CONTROL I	47869
IRCT-4610	RHEUMATOLOGY CONTROL I	47869
IRCT-0047	RHEUMATOLOGY CONTROL II	47869
IRCT-4710	RHEUMATOLOGY CONTROL II	47869
IRFA-0042	RF CALIBRATOR	42230
IRFA-4220	RF CALIBRATOR	42230
IRFA-0230	RHEUMATOID FACTOR	55111
IRFA-5020	RHEUMATOID FACTOR	55111
IRFA-6005	RHEUMATOID FACTOR	55111
ISCA-0250	ISE CALIBRATORS	52867
ISCA-4221	ISE CALIBRATORS	52867
ISCA-4222	ISE CALIBRATORS	52867
ITRF-0400	TRANSFERRIN IP	59041
LACI-0250	LACTATE	53342
LACI-5008	LACTATE	53342
LACI-6005	LACTATE	53342
LDLL-0011	CHOLESTEROL LDL 2G CALIBRATOR	41728
LDLL-0041	CHOLESTEROL LDL 2G CALIBRATOR	41728

Annex

REF	PRODUCT NAME	GMDN Code
LDLL-0230	CHOLESTEROL LDL SL 2G	53395
LDLL-0380	CHOLESTEROL LDL SL 2G	53395
LDLL-0390	CHOLESTEROL LDL SL 2G	53395
LLSL-0230	LDH-L SL	53072
LLSL-5220	LDH-L SL	53072
LLSL-6050	LDH-L SL	53072
LLSL-0400	LDH-L SL	53072
LLSL-5400	LDH-L SL	53072
LLSL-6250	LDH-L SL	53072
LLSL-0420	LDH-L SL	53072
LLSL-M230	LDH IFCC	53072
LLSL-5M30	LDH IFCC	53072
LLSL-6M10	LDH IFCC	53072
LPSL-0230	LIPASE SL	53108
LPSL-0250	LIPASE	53108
LPSL-5088	LIPASE	53108
LPSL-6061	LIPASE	53108
LPSL-0850	LIPASE ENVOY	53108
LXCR-0112	CRP LATEX	53707
MAGX-0230	MAGNESIUM XYLIDYL	46795
MAGX-0600	MAGNESIUM XYLIDYL	46795
MAGX-0850	MAGNESIUM ENVOY	46795
MGXB-0250	MAGNESIUM XB	46795
MGXB-5220	MAGNESIUM XB	46795
MGXB-0600	MAGNESIUM XB	46795
MGXB-5600	MAGNESIUM XB	46795
MGXB-M430	MAGNESIUM XB	46795
MGXB-5M30	MAGNESIUM XB	46795
PASL-0230	ALP (DEA) SL	52928
PASL-5220	ALP (DEA) SL	52928
PASL-6050	ALP (DEA) SL	52928
PASL-0400	ALP (DEA) SL	52928
PASL-5405	ALP (DEA) SL	52928
PASL-6255	ALP (DEA) SL	52928
PASL-0420	ALP (DEA) SL	52928
PHOS-0230	PHOSPHORUS	59123
PHOS-5220	PHOSPHORUS	59123
PHOS-0600	PHOSPHORUS	59123
PHOS-5600	PHOSPHORUS	59123
PHOS-M430	PHOSPHORUS	59123
PHOS-5M30	PHOSPHORUS	59123
PIVD-0850	ALP ENVOY	52928
PROB-0250	TOTAL PROTEIN PLUS	53985
PROB-5220	TOTAL PROTEIN PLUS	53985
PROB-0600	TOTAL PROTEIN PLUS	53985
PROB-5600	TOTAL PROTEIN PLUS	53985
PROB-0700	TOTAL PROTEIN PLUS	53985
PROB-5700	TOTAL PROTEIN PLUS	53985
PROB-M830	TOTAL PROTEIN	53985
PROB-5M30	TOTAL PROTEIN	53985
PRTU-0022	MICROPROTEIN PLUS Standard 100 mg/dL	53482
PRTU-0250	MICROPROTEIN PLUS	53481
PRTU-0600	MICROPROTEIN PLUS	53481
PRTU-5600	MICROPROTEIN PLUS	53481
PRTU-M230	URINE PROTEIN	53481
PRTU-5M30	URINE PROTEIN	53481
RHFA-M130	RHEUMATOID FACTOR	55111
RHFA-5M30	RHEUMATOID FACTOR	55111
RHFA-6M30	RHEUMATOID FACTOR	55111
RHFA-4220	RHEUMATOID FACTOR	42230
TGML-0250	TRIGLYCERIDES SL	53460
TGML-5220	TRIGLYCERIDES SL	53460
TGML-0425	TRIGLYCERIDES MONO SL NEW	53460
TGML-5415	TRIGLYCERIDES MONO SL NEW	53460
TGML-0427	TRIGLYCERIDES MONO SL NEW	53460
TGML-0455	TRIGLYCERIDES SL	53460
TGML-0497	TRIGLYCERIDES MONO SL NEW	53460
TGML-5515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0515	TRIGLYCERIDES MONO SL NEW	53460
TGML-0517	TRIGLYCERIDES MONO SL NEW	53460
TGML-0700	TRIGLYCERIDES MONO SL NEW	53460
TGML-5710	TRIGLYCERIDES MONO SL NEW	53460
TGML-0707	TRIGLYCERIDES MONO SL NEW	53460
TGML-M690	TRIGLYCERIDES	53460
TGML-5M90	TRIGLYCERIDES	53460
TIBC-0250	Direct TIBC	53904
TIBC-5025	Direct TIBC	53904
TIBC-6007	Direct TIBC	53904
TIBC-M130	Direct TIBC	53904

Annex

REF	PRODUCT NAME	GMDN Code
TIBC-5M30	Direct TIBC	53904
TIBC-6M30	Direct TIBC	53904
TRF2-M230	TRANSFERRIN	59041
TRF2-5M30	TRANSFERRIN	59041
TRF2-6M10	TRANSFERRIN	59041
URSL-0250	UREA UV SL	53587
URSL-5220	UREA UV SL	53587
URSL-6050	UREA UV SL	53587
URSL-0420	UREA UV SL	53587
URSL-5405	UREA UV SL	53587
URSL-6255	UREA UV SL	53587
URSL-0427	UREA UV SL	53587
URSL-0455	UREA UV SL	53587
URSL-0500	UREA UV SL	53587
URSL-5505	UREA UV SL	53587
URSL-6605	UREA UV SL	53587
URSL-0507	UREA UV SL	53587
URSL-M830	UREA	53587
URSL-5M30	UREA	53587
URSL-6M10	UREA	53587
VITD-0043	VITAMIN D CALIBRATOR SET	54474
VITD-4311	VITAMIN D CALIBRATOR SET	54474
VITD-4312	VITAMIN D CALIBRATOR SET	54474
VITD-4313	VITAMIN D CALIBRATOR SET	54474
VITD-4314	VITAMIN D CALIBRATOR SET	54474
VITD-4315	VITAMIN D CALIBRATOR SET	54474
VITD-0049	VITAMIN D CONTROL SET	54475
VITD-4630	VITAMIN D CONTROL SET	54475
VITD-4730	VITAMIN D CONTROL SET	54475
VITD-0250	VITAMIN D	54476
VITD-5021	VITAMIN D	54476
VITD-6005	VITAMIN D	54476

vlo
Ce



Declaration of Conformity



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

Declare under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	Clinical chemistry analyzer, automated
Model	Selectra ProM
Reference numbers	6003-400
GMDN code	56678
Accessories	See separate document 'Regulatory status of parts & accessories'

Product classification

As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure

In accordance with Annex III of the IVDD 98/79/EC

The product (including all accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL);
- All other member states of the European Union (EU);
- All member states of the European Free Trade Association (EFTA) and Switzerland.

Spankeren, August 2015

A. Altink
Managing Director



Declaration of Conformity



List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	EN ISO 13485:2012	Medical devices—Quality management systems— Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems— Requirements for regulatory purposes.	

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.™

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS
Zone Industrielle
61500 SEES FRANCE

pour les activités
for the activities

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

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

réalisées sur le(s) site(s) de
performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date : July 25th, 2023 (included)

Valable jusqu'au / Expiry date : July 27th, 2026 (included)

Etabli le / Issued on : July 25th, 2023

cofrac

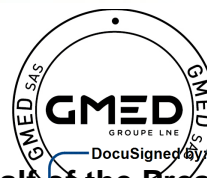


Accréditation n°4-0608
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 10462-8

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

Renouvelle le certificat 10462-7



On behalf of the President
Marjorie PERRIMON
Certification Director

Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

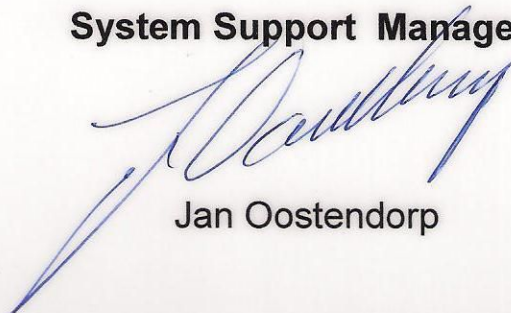
Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

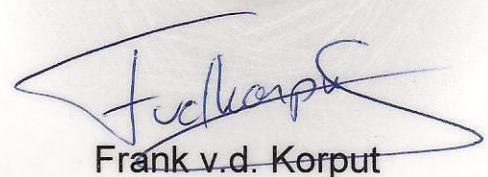
Date of training: April 20th – April 23rd, 2010

System Support Manager:



Jan Oostendorp

System Support Engineer:



Frank v.d. Kerput

ELITechGroup B.V.
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info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

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

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

ELITechGroup B.V.



Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

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



ISO 9001 -NF EN ISO 13485



R E A G E N T S

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, subsemnații Seppim S.A.S., compania producătoare a reagenților Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franța, confirmăm, că reagenții au fost testați și validați pe echipamentele Vital Scientific. Pentru acești reagenți există și protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenții cât și echipamentele sunt certificate CE-IVD.

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați și validați la echipamentele Vital Scientific și noi nu cunoaștem compatibilitatea și 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

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SIRET : 318 365 228 00036

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