Declaration of Conformity

We: **Vital Scientific B.V.**
Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and 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 mark.

Product	**: Clinical chemistry analyzer**
Model	**: Selectra XL**
Catalog No.	**: 6002-600**
GMDN code	**: 56678 (Analyzer)**
	: 56682 (Dry ISE)

Product classification

Products for self declaration (also referred to as: "Other Devices")

Conformity assessment procedure

In accordance with Annex III of the IVDD

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

- The Netherlands (NL)
- All member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA)

Spankeren, February 2011

A.Altink
Managing Director

CE	Declaration of Conformity	ELITechGroup VITAL SCIENTIFIC

List of applied (harmonized) standards

Applied standards		
Safety	IEC 61010-1:2001 Second edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements
	IEC 61010-2-081:2001 First edition	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 First edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical devices
EMC	EN 61326-1:2006	Equipment for measurement, control and laboratory use
	EN 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
	EN55011:2007	Emission – class A
	EN 61000-3-2:2006	Limit for harmonic currents emissions
	EN 61000-3-3:1995 +A1:2001, +A2:2005	Limitation of voltage fluctuations and flicker
	EN 61000-4-2:1995 +A1:1998, +A2:2001	Electrostatic discharge (ESD) immunity
	EN 61000-4-3:2006	Radiated electromagnetic field immunity
	EN 61000-4-4:2004	Electrical fast transient (EFT) immunity
	EN 61000-4-5:2006	Surge transient immunity
	EN 61000-4-6:1996 +A1:2001	Conducted Radio-Frequency disturbances immunity
	EN 61000-4-11:2004	Voltage dips and interruptions immunity
User Manual	EN 591:2001	In vitro diagnostic systems – Requirements for user manuals for in vitro diagnostic instruments for professional use.
Performance	EN 13612:2003	Performance evaluation of IVD medical devices
Symbols	EN 980:2003	Graphical Symbols for use in the labeling of medical devices
Risk analysis	ISO 14971:2007	Medical devices - Application of risk management to medical devices
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.
	ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.

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:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ("IVD Directive")
- 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")

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

Product	**Clinical chemistry analyzer, automated**
Model	**Selectra ProM**
Reference numbers	**6003-400** (Break-in number from 17-7503)
GTIN	**03661540600302**
GMDN code	**56678**
Accessories	**See Annex**

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 IVD Directive
- Article 4 of the RoHS2 Directive

Spankeren, January 2018

Maurice Verdaasdonk

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control and laboratory used – Part 2-010: particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2015	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 61010-2-101:2015	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 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	
	IEC 61326-2-6:2006	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.	

Declaration of Conformity

Annex – List of IVD accessories

EGBV PART NUMBER	DESCRIPTION
3201-019	Precision Test Solution

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra ProM - Unpacking and Installation

17/03/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

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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 (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 Reglementarios

ELITech Clinical Systems SAS
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SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

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

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

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

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

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

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

V1a
CB

Certificate of Registration

This certificate has been awarded to

AO Vector-Best

1/1, Arbuzova str., Novosibirsk, 630117, Russian Federation

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Design and Development, Production and Distribution of In Vitro Diagnostic Medical Devices (ELISA, PCR, Clinical Chemistry)

Certificate Number **209535/A/0002/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
05 October 2022	1	04 October 2025	1
Revision Date	**Revision Number**	**Original Certificate Issue Date**	**Scheme Number**
06 October 2022	1	05 October 2022	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by

On behalf of the Schemes Manager

UKAS MANAGEMENT SYSTEMS 0043

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.
370 West 1700 South
Logan
Utah
84321
USA

Facility ID Number: F000174

Holds Certificate No: **MDSAP 689350**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

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: 2019-03-28 Effective Date: 2022-01-11 Expiry Date: 2025-01-10

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

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 spares and 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**
Product No.	**: 6003-400**
Model	**: Selectra ProM**
GMDN code	**: 56678**

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

The product (including all spares and 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 other states that are part of the European Economic Area (EEA), including Switzerland

Spankeren, March 2015

A. Altink

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Certification 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	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	DEKRA
	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 8

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**

On behalf of the President,
Marjorie PERRIMON
Certification Director

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

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

Renouvelle le certificat 10462-7

GMED_SQ-F-V0-07-2018

ELITechGroup
VITAL
SCIENTIFIC

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. Korput

SPECIFICATIONS

THROUGHPUT
- Up to 266 tests / hour;
- Up to 180 photometric tests / hour in MONO mode.

REAGENT SYSTEM
- Refrigerated reagent rotor controlled with Peltier elements;
- Cooled to 10°C+/-2°C at normal laboratory conditions;
- 32 reagent positions for 10 ml, 25 ml and 50 ml reagent bottles;
- Reagent ID and automated programming of assays and calibrators via barcode;
- Typical reagent consumption 250 ul per test;
- All reagent positions can be assigned as R1, R2 and R3;
- Pre-heated needle with level detection, collision protection and integrated mixer.

SAMPLE SYSTEM
- Sample rotor containing:
  - Outer segment with 50 barcode readable positions
  - Inner segment with 12 auxiliary positions
  - All positions fit 13x75 mm primary and secondary tubes and pediatric cups
  - All positions can be used for Calibrators, Controls, Normal, Pediatric and STAT samples;
- Sample probe with level detection, integrated mixer and collision protection;
- Programmable dilution rations 1:5 up to 1:200 in one step increments with 3 possible diluents.

PIPETTING SYSTEM
- 1000 µl Reagent syringe:
  - R1 volume 110 - 400 µl;
  - R2 volume 0 - 180 µl;
  - R3 volume 0 - 180 µl;
  - Programmable in 1 µl steps;
- 100 µl Sample syringe;
  - Sample volume 1-30 µl;
  - Programmable in 0.1 µl steps.

CUVETTE ROTOR
- Cost effective, semi-disposable cuvette rotor with 48 cuvettes, path length 7mm;
- >10.000 tests per rotor;
- Minimum measuring volume 220 µl;
- Measuring temperature 37˚C, controlled by Peltier elements.

LIGHT SOURCE
- Quartz-iodine lamp 12V-20W.

WAVELENGTH RANGE
- 340 - 800 nm;
- Optical unit with 8 position filter wheel;
- Automatic wavelength selection
- 340, 405, 505, 546, 578, 620, 660, 700 nm standard installed;
- Other wavelenghts available on request.

PHOTOMETRIC RANGE
- -0.1 to 3.0 Absorbance;
- Resolution 0.001 Abs.

ANALYTICAL MODES (SINGLE, DUAL AND TRIPLE REAGENT SYSTEM)
- Kinetic measurement with linearity check;
- Mono- and bichromatic end point measurement with or without bichromatic reagent blank and/or sample blank correction;
- Two point measurement; with or without slope blank;
- Graphic plot of all measuring points;
- Predilution and automatic reflex dilution as needed;
- Non-linear calibration curves;
- Prozone check for immunology tests;
- Cut-off declaration;
- Calculated tests.

QUALITY CONTROL
- Up to 15 different controls can be defined, 3 per test;
- Westgard rules;
- Levey-Jennings plots;
- Quality control statistics.

WATER CONSUMPTION
- ~500 mL per hour max, continous operation.

STANDARDS AND REGULATIONS
- CE-IVD;
- CB.

DIMENSIONS (BENCHTOP, SELF CONTAINED UNIT)
- 122 x 75 x 61 cm (W x H x D);
- Weight: 95 kg.

INTERFACE
- Host: RS232 or Ethernet (TCP/IP) through LIS-2A protocol.

ENVIRONMENTAL CONDITIONS
- Temperature: 15 – 32 °C;
- Humidity: 15 – 85% RH;
- Altitude: up to 2000 m;
- Plumbing: No dedicated system water or drain required;
- Electrical:
  - Voltage: 100 – 240 Vac;
  - Frequency: 50 – 60 Hz;
  - Power (max): 380 VA.

INTEGRATED PC
- Operating System: MS Windows™ XP.

BAR CODE READER
- Hand held CCD bar code reader used for test requisition, reagent identification and automated programing of assasys, controls, and calibrators.

OPTIONS

DRY ELECTRODE ISE MODULE
- Patented Solid State Electrode Technology;
- Indirect Measurement
- Dilution 1:14;
- Measures Sodium, Potassium, Chloride and CO2.

POSITIVE SAMPLE IDENTIFICATION
- Positive Sample Identification (PSID) via integrated barcode reader. Reads all popular formats including Codes 39, 128, 11, 93, 4, CODABAR, and Interleaved 2/5.

PRINTER
- Printer supported by MS Windows™.

ECO KIT
- Enables separate collection of concentrated measurement mixture and dilute (wash) waste.

About ELITechGroup Clinical Systems...

ELITechGroup Clinical Systems is a global leader in BenchTop Chemistry Systems, with over 15,000 Chemistry Systems delivered.
Our mission is to enable better medical decisions by bringing high-value diagnostic solutions and services to laboratories that are closer to the patient (proximity laboratories).
ELITechGroup Clinical Systems leadership originates from our ability to continuously provide differentiated products and services focused to meet the needs of proximity laboratories. ELITechGroup Clinical Systems markets the Selectra Pro Series, designed to deliver trouble-free results laboratories can trust.

Delivering Trouble-Free Results Laboratories can Trust

Robust, Always gets the job done	Trouble-Free Operations	Right Results, On Time
✓ True workhorse with proven system reliability	✓ Simplifies lab operations & reduces error	✓ Designed with mistake proofing and error reducing capabilities
✓ Support you can count on	✓ Best vendor services, application & lab operations support	✓ Management of difficult samples
✓ Best in class operator interface, easy to train, operate & maintain	✓ Cost effective, minimizes labor, maintenance & waste	✓ Proven methodologies, referenced and traceable to industry standards

The Selectra Pro Series builds on the established robustness and reliability of the current Selectra systems, resulting from decades of proven experience in the design and manufacture of award winning BenchTop laboratory products. Together with a dedicated range of ready-to-use reagents from ELITech Clinical Systems, the Selectra Pro Series provides an ideal chemistry solution for laboratories that are closer to the patient.

Over the past decades, the ELITech Group Companies have established a solid distribution network that operates world-wide. Thousands of customers have experienced the quality, convenience and reliability of ELITech products. Local support is provided by dedicated and well trained sales and service organizations.

Distributor contact information:

Part nr: 6003-700-490-2014/02 EN

WORLDWIDE OFFICES

Headquarters	**T: +33 1 41 45 07 13**		
Australia	T: +61 1800 815 098	New Zealand	T: +64 800 555 611
Benelux	T: +31 313 430 574	Serbia	T: +381 11 2467119
Brazil	T: +55 27 3025 1415	Switzerland	T: +41 26 663 86 60
France	T: +33 4 83 36 10 82	The Netherlands	T: +31 313 430574
Italy	T: +39 02 48 40 35 42	UK	T: +44 1442 869320
Middle East & Africa	T: +971 4 375 2744	United States	T: +1 609 216 7361

ELITechGroup
SOLUTIONS
tailored to your needs
www.elitechgroup.com
info@elitechgroup.com

CLINICAL SYSTEMS

Selectra ProM

SELECTRA PROM
CHEMISTRY SYSTEM

Delivery trouble free results Laboratories can trust

ELITechGroup
CLINICAL SYSTEMS

Selectra ProM System

Setting the new standard in BenchTop Chemistry Systems, the Selectra ProM offers a robust new compact design, with best in class operator interface. New system features enable significant productivity and performance enhancements not typically found in BenchTop Chemistry Analysers.

Together with a superior menu of ready-to-use stable-liquid reagents from ELITech Clinical Systems, the new Selectra ProM System provides a state of the art, fully integrated chemistry solution for laboratories that are closer to the patient.

With random access throughput up to 266 tests per hour, the Selectra ProM System is the ideal BenchTop workhorse for primary, STAT or back-up testing needs. This new system offers minimal maintenance and effective use of consumables to truly reduce operational cost.

Building on the successful Selectra Family, the Selectra ProM Chemistry System offers an ideal solution of proven quality, performance and value to get the job done with results laboratories can trust, every time and on time.

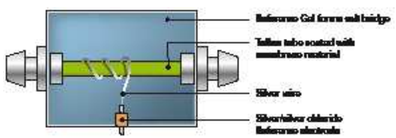
- ✓ New world class operator interface simplifies operation
- ✓ New compact integrated design - fully self contained including Command Center, ISE Module, reagent cooling, and on-board waste and water
- ✓ New productivity and error reducing capabilities: on-board PSID, Reagent ID and automated programming of assays, calibrators and controls
- ✓ New designs to improve performance, minimize maintenance and maximize uptime

Simplified operations with growing line of liquid-stable reagents

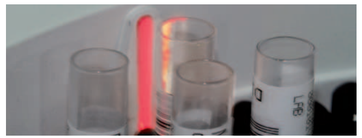
- ✓ Dedicated line of ready-to-use assays, packaged to fit the BenchTop laboratory
- ✓ Tied to proven methodologies, referenced and traceable to industry standards
- ✓ Standardized results across ELITechGroup Clinical Systems SELECTRA Family
- ✓ Commitment to ongoing enhancement to existing methods

Improved laboratories operations

Optimized with ELITechGroup Clinical Systems Reagents
When combined with the broad new ELITechGroup Clinical Systems test menu, the innovative system design increases the user-friendliness and efficiency of the Selectra ProM. The enhanced reagent supply provides flexibility in reagent containers and increased on-board stability. New features enable automated programming of assays, with bar coded reagents, calibrators and controls, streamlining operations and reducing error. Optimum sized packaging further enhances efficiency.



Integrated State of the Art Dry ISE Technology
Patented solid state electrodes have permanent gel which limits routine priming of ISE reference solutions as they can be left dry when not in use. This reduces reagent consumption and improves cost effectiveness. The Selectra ProM ISE design incorporates new control software and hydraulics which significantly enhances performance and reliability.



On-board PSID and data management features
PSID is one of the most effective productivity and error reducing capabilities in modern laboratory operations. The Selectra ProM brings on-board PSID to BenchTop Laboratories. Together with advanced data management features like our host-query LIS interface, versatile barcode based PSID eliminates the tedious job of programming samples and error prone matching of sample positions. Tests can be autovalidated versus laboratory defined parameters, improving walk-away operation and further increasing confidence in the results.

New Designs to enhance performance, reliability, and reduce maintenance
- ✓ Improved level sensing and metering performance
- ✓ Improved reagent thermal control
- ✓ Longer life designs of key components reduces cost and cuts preventive maintenance service time in half
- ✓ Improved method performance for TP, Magnesium and ISEs

Superior Test Menu*

General Chemistry	ALT/GPT, ALP , Amylase, AST/GOT, CK-MB, CK-NAC, GGT Plus, LDH-L
	Albumin, Bilirubin Direct, Bilirubin Total, Cholesterol, Cholesterol HDL, Cholesterol LDL,
	Creatinine, Glucose, Microprotein Plus, Total Protein Plus, Triglycerides, Urea UV, Uric Acid
	Calcium, Iron, Magnesium, Phosphorus
Specific Proteins	C-reactive Protein, Haptoglobin, HbA1C, IgA IP, IgG IP, IgM IP, Microalbumin, Orosomucoid,
	Prealbumin, Transferrin
Ion Selective Electrodes	Carbone Dioxide, Chloride, Potassium, Sodium

*Subject to regulatory clearance for some markets.

Simplicity that drives productivity

Best in Class Operator Interface

Selectra Systems are known for easy-to-use software, and the Selectra ProM sets a new standard for software navigation and operator interface. Touch screen operated with a next generation design, the state of the art software significantly boosts laboratory productivity.
The software is designed to have intuitive ease of use across a wide range of laboratory settings, from labs with basic IT to operations with fully automated informatics, from new operators to those with deep experience.
Intuitive icons guide the operator through their workflow and color coded graphic and audible alerts highlight conditions that operators need to know. Details are just a touch away.

Taking software to the next level
The intuitive simplicity designed into the software enables inexperienced staff to operate the Selectra ProM within an hour. Interactive routines lead the operator to the results quickly. Simplified operation brings new staff up to speed quickly, delivers continuous productivity improvements, and reduces errors.

- ✓ The unique combination of PSID, host-query LIS interface and programmable result checks dramatically improves walk-away time and reduces sample and test request entry and associated errors.
- ✓ Customizable start and end-of-day checklists guide operators through daily tasks, tracking upcoming maintenance, inventory on-board, and expiring calibrations and reagents.
- ✓ Operators' manual and system maintenance instructions are integrated in the software. Touch HELP on your daily checklist and the system links you directly to the instructions.
- ✓ To further optimize productive laboratory time, the system is capable of Remote Diagnostics, and will have software aided service adjustments and performance tests to maximize uptime.

THE NEW STATE OF THE ART IN BENCHTOP CHEMISTRY, SOFTWARE DESIGNED TO DELIVER TROUBLE FREE RESULTS LABORATORIES CAN TRUST

ELITechGroup
A BRUKER COMPANY

CHEMISTRY WORKSTATION

selectra® XL

Performance. Value.

overview & assay menu

Why choose the Selectra XL?

The Selectra XL delivers what your laboratory needs - an economical solution for your chemistry testing that doesn't sacrifice performance and reliability. The Selectra XL is built on the proven Selectra platform which has resulted in over 5000 installations worldwide, giving your lab proven reliability and peace of mind. In addition, with a throughput up to 480 tests per hour, random access with STAT capability, and a comprehensive test menu, the Selectra XL provides the performance and flexibility you require.

Features that save time and money.

High throughput
Comprehensive test menu
Dry Electrode
Reusable cuvettes
Self-contained water supply
On board reagent cooling
Low reagent usage
Internal barcode reader
Easy-to-use operating software
Random access
Continuous loading
Pre-dilution and automatic rerun
Interactive maintenance procedures
4 hours walk-away operation
Positive patient identification
Reagent barcode scanning
Primary tubes
STAT handling
Reagent level sensing
Test incompatibility

Testing capability you need.

The Selectra XL has a comprehensive test menu, providing your laboratory with the testing options you need. Vitalab brand reagents, the highest quality reagents available, will ensure the accuracy and reliability of your results. In addition, because of the highly precise measurement system, on board mixing and open channels, the Selectra XL gives you the ability to add specialty assays.

Available reagents.

General Chemistry Assays
Albumin
Bilirubin, Direct
Bilirubin, Total
Calcium
Creatinine
Glucose
HbA1c
Iron, Total
Magnesium
Phosphorus
Protein, Total
Urea Nitrogen (BUN)
Uric Acid

Enzyme Assays
Alanine AminoTransferase (ALT)
Alkaline Phosphatase
Amylase
Aspartate Transaminase (GOT)
Creatine Phosphokinase (CPK)
Gamma Glutamyl Transferase (GGT)
Lactate Dehydrogenase (LDH)

Lipids Assays
Direct LDL
Triglycerides
Direct HDL
Cholesterol

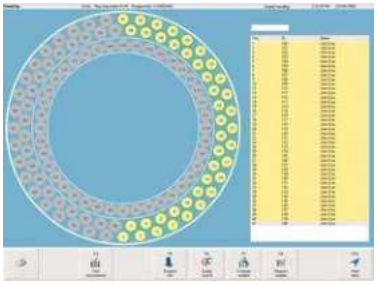
Electrolyte Assays
Carbon Dioxide
Chloride
Potassium
Sodium

Theraputic Drug Assays
Digoxin
Phenobarbital
Phenytoin
Theophylline

In Development
hsCRP; Apolipoprotein A1; Apolipoprotein B; Iron, TIBC

selectra® XL

features & benefits



Easy-To-Use Software

Selectra XL software is Windows® based, simple and straightforward, providing uncomplicated operation of the instrument. Quality Control results are stored in memory and easily displayed on the screen. Results are validated using Westgard rules and displayed with a Levey-Jenning Plot.

Open Channels

The Selectra XL provides user-definable open channels, allowing for the addition of specialty assays.

Reagent Rotors

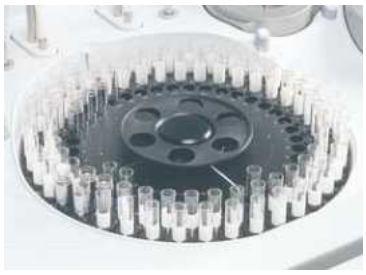
The Selectra XL, with two 32 position reagent rotors, holds 64 individual Vitalab reagents, providing up to 4 hours of walk-away operation. On-board cooling of the reagent chamber assures reagent stability, providing reliable results while lowering cost. Continuous inventory monitoring enables the operator to know the number of tests remaining for each reagent, minimizing waste and lowering laboratory cost.

Reusable Cuvette Rotors

The Selectra XL has two 48 position semi-disposable cuvette rotors, which only need to be replaced after 10,000 tests. The cuvette rotors are automatically washed on board, creating significant cost savings by eliminating need for expensive disposable cuvettes.

On Board Wash System

The automated, on board cuvette wash, eliminates the need for an external water system, reduces contamination, and provides a cost-effective, high-quality result.



High Capacity Sample Rotor

The Selectra XL sample wheel contains 80 barcode read sample positions, which are available for primary draw tubes or disposable sample cups, and 30 positions for calibrators and controls.

Internal Barcode Reader

The Selectra XL features an internal barcode reader, eliminating manually entry of samples, saving your laboratory significant time.

Vitalab Dry Electrode™

The Vitalab Dry Electrode is a proven, dry, solid-state ISE (Ion Selective Electrode) for Na^+, K^+, Cl^- and CO_2, providing a complete test panel without adding an enzymatic procedure or using a traditional 'wet' electrode, which significantly reduces cost and maintenance time, while increasing reliability of results.

technical specifications

Throughput
- Up to 480 tests per hour.

Reagent system
- Two Rotors with each 24 positions for 25 ml bottles and 8 positions for 5 ml bottles. All positions can be assigned as R1 and R2. Adapters for 5 ml bottles in 25 ml positions.
- 10 pairs of 25 ml positions can be used for 50 ml bottles.
- Reagent 1 volume 110 - 400 µl
- Reagent 2 volume 0 - 180 µl
- Reagent disk compartment is cooled to approx. 12°C below ambient temperature.
- Preheated reagent needle with level detection and integrated mixer.
- Typical reagent consumption 250 µl per test.

Sample system
- Sample rotor containing :
  - 80 barcode read samples positions
  - inner ring for
  . 20 calibrators;
  . 10 controls;
- Stat and pediatric functionality
- Continuous loading
- Internal barcode reading
- Primary tubes (13 or 16 mm OD)
- All positions can contain 5 ml or 10 ml primary tubes or sample cups.
- Sample volume 1 - 30 µl per test, programmable in steps of 0.1 µl.
- Sample probe with level detection and integrated mixer.

Sample predilution
(Dual mode only)
- Programmable ratios 1:5, 1:10, 1:20, 1:30, 1:40, 1:50, 1:100 with 3 possible diluents.

Pipetting system (2)
- Hamilton syringes and valve block.
- Reagent syringe 1000 µl.
- Sample syringe 100 µl.

Reaction disks (2)
- Semi-disposable rotor with 48 cuvettes. Path length 7 mm.
- Minimum measuring volume 220 µl.
- Measuring temperature 37°C, controlled by Peltier elements.

Washing units (2)
- Cuvette-washing with 4 x 500 µl of water. The unit is equipped with liquid sensors. Cuvettes are dried before use.

Light source
- Quartz-iodine lamp 12V-20W.

Wavelength range
- 2 optical units each with a 8 position filter wheel
- Automatic wavelength selection by 8-position filterwheel (340, 376, 405, 505, 546, 578, 640 and 700 nm). Half bandwidth 8 to 12 nm.
- Other wavelengths on request

Photometric range
- -0.1 to 3.0 Absorbance

Analytical modes
- Kinetic measurement with linearity check.
- Bichromatic end point measurement with or without bichromatic reagent blank and/or sample blank correction.
- Two point measurement.
- Graphic plot of all measuring points.
- Automatic rerun with sample reduction.
- Non-linear calibration curves

Ambient temperature
- 15 - 32°C.
- Maximum humidity 80%.

Measurement capabilities
(Single reagent mode)
- Reagent Absorbance (Bichromatic) before sample addition.
- Kinetic during 7 minutes after sample addition.
- End Point (Bichromatic) 11.5 minutes after sample addition.
- Kinetic can contain two points for two-point measurements

Measurement capabilities
(Dual reagent mode)
- Reagent Absorbance (bichromatic) before sample addition.
- Kinetic 1 for 4.5 minutes after sample addition (can be used as sample blank for Kinetic 2).
- Kinetic 2 for 4 minutes after reagent 2 addition.
- Kinetic 1+2 for 8.5 minutes after sample addition.

Calculation modes
- Prozone check for immunology tests.
- Cut-off declaration.

Quality control
- Up to 15 different controls can be defined, 3 per test.
- Westgard rules.
- Levey-Jennings plots.

Standards
- CE
- CB certificate

Languages
- English, Spanish, French

Dimensions
45 x 45 x 30 inches
(W x H x D excl. Monitor)

ISE Specification

Power Requirement
- 100 W.

Ambient Temperature
- 10 - 32°C.
- Maximum humidity 85%.

Dimensions and Weight
- 9 x 12 x 11.5 inches (W x H x D).
- 14 lbs.

Parameters
- K, Na, Cl, CO_2
- Sample Type: Serum or Plasma.
- Sample Volume: 25 µl.
- Diluent Volume: 325 µl.
- Measurement cycle time: 40-50 secs.
- Calibration cycle time: 300-450 secs.
- Wash cycle time: 2000 secs.

contact us

ELITechGroup is a global leader in *in-vitro* diagnostics, serving hospitals and diagnostic laboratories in over 100 countries through a direct sales network and trusted distribution partners. The company develops, manufactures, and markets a comprehensive range of diagnostic products and solutions, including instruments, reagents, and software.

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