Anexa 1 la formularul Specificatii Tehnice Anexa 23

Lotul nr. 1 Analizator biochimic automat sistem de tip inchis

Nr.	Denumire produs	Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi			Specificații tehnice oferite
	Analizator biochimic, automat cu sistem de tip inchis	**Descriere**		Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi	Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi, model Selectra ProS (Elitech/Olanda)
		Parametru		**Specificația**	
		Tip de lucru		continuu	continuu
		Tip sistem		inchis	inchis
				randoom acces	Random acces
		Capacitatea (teste/oră)		≥ 150 (teste fotometrice, fără modulul ISE)	133 (teste fotometrice, fără modulul ISE) 266 (teste fotometrice, cu modulul ISE)
		Posibilitatea efectuarii analizelor urgente		da	da
		Tipul dispozitivului		staţionar	staţionar
		Tip probă		Ser şi plasmă	Ser şi plasmă
				urină	urină
				sînge integru / hemolizat	sînge integru / hemolizat
				CSF (lichid cefalo-rahidian)	CSF (lichid cefalo-rahidian)
		Tip diluare		automat	automat
		Sistem de spălare	**Automat**	da	da
			Fara conectare la sursa externa de apa		
			Volumde apa consumat per ora	≤0.5L	da
		Program control al calității	**Management intern al controlului calitatii**	da	da
			Grafice Levey-Jennings	da	da
		Compartiment reactivi	**Cantitate de reactivi concomitent la bord**	≥30	Da, 30
			Capacitatea buteliilor cu reactivi	20ml si 50ml	10 mL, 25 mL si 50 mL reagent
			Detectia nivelului de lichid	da	da

			Consum de reagent poate fi programat	10µl - 440µl	Da, cu pas de 0.1 µL
		Compartiment probe	**Cantitate probe la bord**	≥72	25
			Eprubete primare	da	da
			Eprubete pediatrice	da	da
			Eprubete primare si pediatrice pot fi utilizate concomitent	da	da
			Volum proba	3-40 µL	1 - 30 µL
		Rotor cu încălzire pentru probe	**cu termostat la 37 grade C**	da	Cu termostat la 37 grade C
			Cantitatea celulelor pentru reactie	≥120	da
			De o singura folosinta	da	>10,000 tests per rotor
			Volum de reactie	200 µL – 800 µL	da
		Regimuri de măsurare	**cinetic**	da	da
			mono și bi-cromatic	da	da
			imunoturbidimetrc (Turbidity)	da	da
			Filtre optice utilizate	≥8	da
			Diapazonul filtrelor	340nm – 900nm	Da, 340nm – 800nm
			Functie de detectie a proznei	da	da
		Sistem operational	**Calculator extern**	da	Calculator integrat in analizor
			Interfata LIS	da	da
			Program intuitiv si usor de utilizat	da	da
			Sensor de obstacol	da	da

		Sistem de dozare	**Volum de dozare**	3 µL – 1250 µL	
			rezolutia	≤0.126 µL	0.001 Abs
			Viteza de dozare	≥880 µL/s	da
		Lampa halogen		6 V, 10W	Da, Quartz-iodine lamp 12V-20W
		Durata de viata		≥2000 ore	da
		Reactive biochimice pentru analizatorul biochimic automat cu system închis		2500 teste	Reactive biochimice pentru analizatorul biochimic automat cu system închis – 2500 teste

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra ProS - Periodic Maintenance and Configuration

02/04/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra ProS - Introduction and Overview

17/03/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
		Selectra ProS							
DM000422656	ANALIZATOR BIOCHIMIC	Selectra ProS™	[LITE]	6003-548	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422652	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/PSID/ISE]	6003-500	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422653	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/PSID]	6003-541	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422655	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O]	6003-543	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422657	ANALIZATOR BIOCHIMIC	Selectra ProS™	[C/PSID/ISE/US]	6003-600	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023
DM000422654	ANALIZATOR BIOCHIMIC	Selectra ProS™	[O/ISE]	6003-542	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000012	18-01-2023

EU Declaration of Conformity

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

declares under sole responsibility that the IVD medical devices specified below (including the listed accessories) and to which this declaration relates, conform to the provisions of:

- **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ("**IVDR**")
- **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 ("**RoHS**").

These IVD medical devices carry the CE-marking and are notified in accordance with the IVDR.

Catalogue number	Description	GTIN
6003-500	Selectra ProS™ [O/PSID/ISE]	3661540 60032 6
6003-541	Selectra ProS™ [O/PSID]	3661540 60490 4
6003-542	Selectra ProS™ [O/ISE]	3661540 60491 1
6003-543	Selectra ProS™ [O]	3661540 60492 8
6003-548	Selectra ProS™ [LITE]	3661540 60493 5
6003-600	Selectra ProS™ [C/PSID/ISE/US]	3661540 60041 8

Product	Chemistry analyzers
EMDN code	W02010101
GMDN code	56676
Intended purpose	Automated clinical chemistry analyzer, to be used in combination with specific reagents, for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine, and aqueous standard solutions.
Risk Class	A
Accessories	See Annex I
SRN of manufacturer	NL-MF-000021018
Basic UDI-DI	3661540Pro-series8A

Spankeren, December 2022

Adriaan Intveld

Person Responsible for Regulatory Compliance (PRRC)

CE	EU Declaration of Conformity	ELITechGroup EMPOWERING IVD

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 use - 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	DEKRA
	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	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA

CE	EU Declaration of Conformity	ELITechGroup EMPOWERING IVD

Annex I – List of IVD accessories

Catalogue number	Description	EMDN	GMDN	GTIN
3201-019	Precision Test Solution	W0201010185	58048	3661540 60042 5
6002-706	Cuvette Rotor Set	W0201010180	61033	3661540 60057 9

Lloyd's Register

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

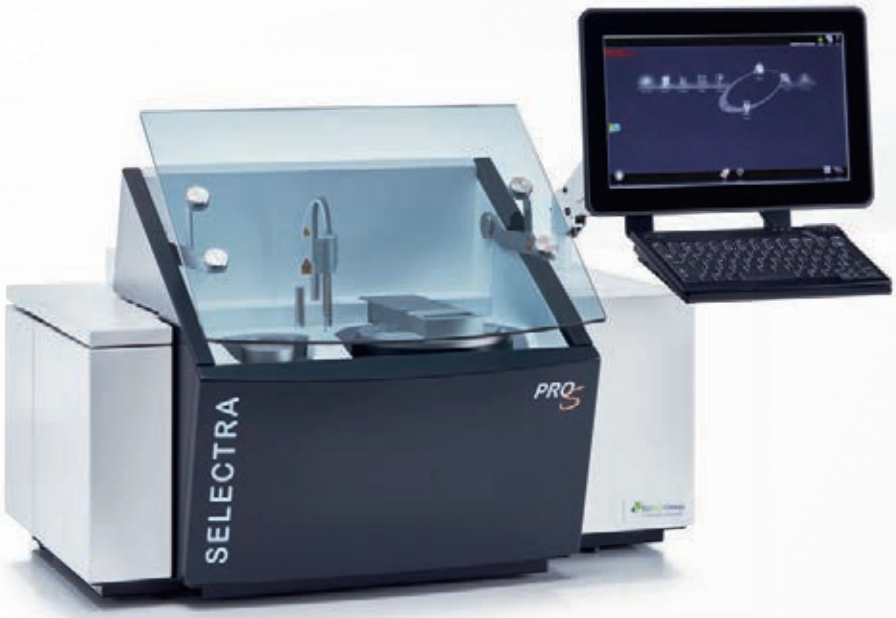
Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate 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

Selectra ProS™

THE SMARTEST CHOICE FOR LABORATORIES LOOKING TO AUTOMATE



Cresce cum fide

Selectra Solutions

Clinical Systems

SPECIFICATIONS

THROUGHPUT
- Up to 133 tests/hour
- Up to 266 ISE tests/hour

REAGENT AND SAMPLE HANDLING
One rotor combining both sample and reagent positions.
- Inner rotor ring:
  - 30 refrigerated reagent positions for 10 mL, 25 mL and 50 mL reagent bottles
  - Cooled to 10°C +/-4°C at normal laboratory conditions
  - All reagent positions can be assigned as R1, R2 and R3
- Outer rotor ring:
  - 25 barcode readable 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

PIPETTING SYSTEM
- 1000 µL reagent syringe:
  - R 1 volume 110 - 400 µL
  - R 2 volume 0 - 180 µL
  - R 3 volume 0 - 180 µL
  - Programmable in 1 µL steps
- 100 µL sample syringe:
  - Sample volume 1 - 30 µL
  - Programmable in 0.1 µL steps
- Programmable dilution ratios: 1 : 5 up to 1 : 200 in one step increments with 3 possible diluents
- Pre-heated probe with level detection, collision protection and integrated mixer

CUVETTE ROTOR
- Cost effective, semi-disposable cuvette rotor with 48 cuvettes, path length 7 mm
- >10,000 tests per rotor
- 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 wavelengths 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, post-dilution 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
- ~950 mL per hour max, continuous operation

STANDARDS AND REGULATIONS
- CE-IVDR
- USA FDA 510(k)
- CB
- UL

DIMENSIONS & WEIGHT
- 90 cm (36 in) x 75 cm (30 in) x 60 cm (24 in) (W x H x D)
- 75 kg (165 lbs)

INTERFACE
- State of the art Host-Query interface available
- Host: RS232 or Ethernet (TCP/IP) through LIS-2A protocol
- Hand held CCD barcode reader used for reagent identification and automated programming of assays, controls and calibrators

INSTALLATION CONDITIONS
- Temperature: 15 - 32 °C (59 - 90°F)
- 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): 400 VA

INTEGRATED PC*
- Touch screen navigation
- Operating System: MS Windows™ Embedded

OPTIONS

ISE MODULE*
- Patented Solid State Dry Electrode Technology
- Indirect measurement
- Dilution 1:14
- Measures Sodium, Potassium, Chloride and Bicarbonate

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™

PROACTIVE MAINTENANCE KIT
- Complete parts kit for annual preventive maintenance

** Please verify the right instrument catalog number for this option from your local representative.*

WORLDWIDE OFFICES
Please email sales.ecsnl@elitechgroup.com or contact your local representative for information on the availability in your area.

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ELITechGroup
EMPOWERING IVD

www.elitechgroup.com

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