## Anexa nr.1 la Formularul Specificații tehnice

## Analizator biochimic, automat 100 teste, cu sistem de tip deschis

| | | |
|---|---|---|
| **Descriere** | Analizator biochimic, automat 100 teste, cu sistem de tip deschis. Cod 150200. Descriere Analizator biochimic automat destinate analizelor biochimice cu sistem deschis deschis de reactive. | |
| **Parametrul** | **Specificația solicitata** | **SPECIFICAȚII TEHNICE OFERTATE**<br>**Selectra ProS (cat. no. 6003-543) (ELITECHGROUP B.V./Olanda)** |
| **Sistem analitic** | Automat, cu calculator integrat sau exterior (procesor, monitor, tastatura+mouse. | Automatizat, cu calculator integrat (procesor, monitor, tastatura+mouse). |
| **Tip de lucru** | continuu | Continuu |
| **Tip sistem** | deschis | deschis |
| | randoom acces | random acces |
| **Capacitatea (teste/oră)** | ≥100 (teste fotomerice, fara modul ISE) | 133 (teste fotomerice, fara modul ISE) |
| **Posibilitatea efectuării analizelor urgente** | da | Da |
| **Tipul dispozitivului** | staţionar | Da |
| **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 | automatizată |
| **Sistem de spălare** | TOTAL automat (cuvă, ac, sistem de dozare) | Total automatizată (cuvă, ac, sistem de dozare) |
| **Program control al calității** | da | Da |
| **Compartiment reactivi cu răcire** | da | Da |
| **Rotor pentru reactie cu încălzire** | cu termostat la 37 grade C | Da |
| **Rotor pentru reactie, (indicați ciclurile posibile de reutilizare)** | da | Da, 10 000 cicluri |
| **Regimuri de măsurare:** | Cinetic | Cinetic |

| | | | |
|---|---|---|---|
| | | Mono și bi-cromatic | Mono si bi-cromatic |
| | | Imunoturbidimetric (Turbidity) | Imunoturbidimetric (Turbidity) |
| | | Controlul cantității de reagent rămas | Controlul cantitătii de reagent rămas |
| **Semnalizare** | | Lipsa reagent si proba | Lipsa reagent si proba. |
| **Sistemul de dozare:** | Reagenții:utilizare a minim 2 metodici: | metodici: mono și bireagent | metodici: mono si bireagent |
| | Volumul reagentului programabil cu pasul 1 µl. | Da | Da |
| | | cu sensor de obstacole | Dispune de sensor de obstacole |
| **Alimentarea** | | 220 V, 50 Hz | 100 - 240 V, 50/60 Hz |

Digitally signed by Ceaicovschi Tudor
Date: 2024.05.02 07:30:43 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | BIOCHIMIC | | | | | B.V. | | | | |
| DM000422655 | ANALIZATOR BIOCHIMIC | Selectra ProS™ | [O] | 6003-543 | Olanda | ELITECHGROUP B.V. | GBG-MLD S.R.L. | Rg04-000012 | 18-01-2023 | |

By Royal Charter

# 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



MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

# 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 |

# 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**

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by:

Marjorie PERRIMON

F6FB7BBEC7B144D...

**On behalf of the President,**
**Marjorie PERRIMON**
**Certification Director**

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

GMED_SQ-F-V0-07-2018

GMED N° 10462–8

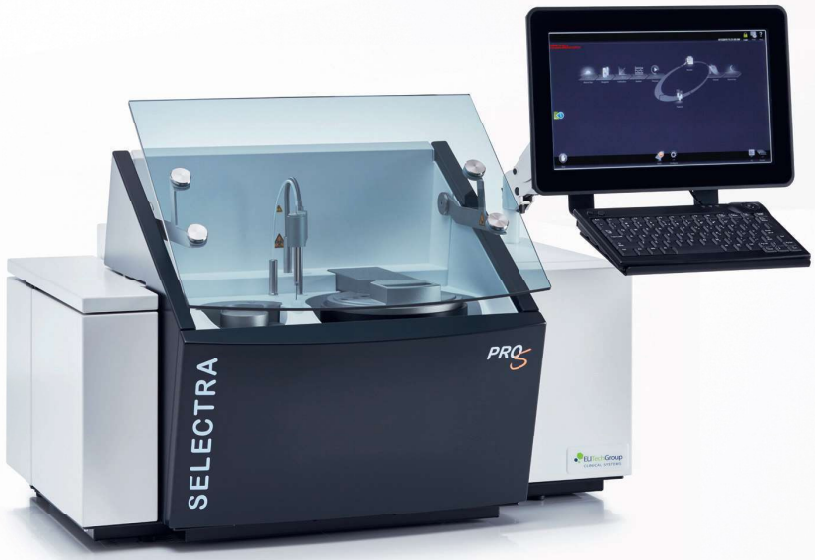
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-7

Clinical Systems

# Selectra Pro S

## 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 - IVDD
- 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


**WORLDWIDE OFFICES**
Please contact your sales representative for terms, conditions and product availability in your country.

| | | | |
|---|---|---|---|
| **Headquarters** | **+33 1 41 45 07 10** | | |
| Australia | 1800 815 098 | New Zealand | 0800 555 611 |
| BELUX | +32 92 820 531 | Serbia | +381 11 2467119 |
| Brazil | +55 27 3025 1415 | The Netherlands | +31 313 430 581 |
| France | +33 4 83 36 10 82 | UK | +44 1442 869320 |
| Italy | +39 011 97 61 91 | United States | +1 800 453 2725 |

ELITechGroup
EMPOWERING IVD

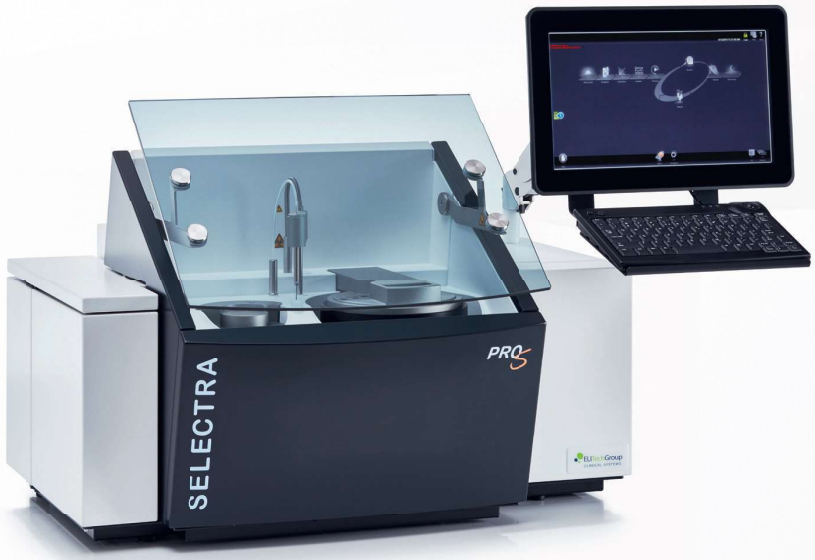
**www.elitechgroup.com**
**info@elitechgroup.com**


6003-500-490-02 EN

Clinical Systems

# Selectra Pro S

## 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 - IVDD
- 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


**WORLDWIDE OFFICES**
Please contact your sales representative for terms, conditions and product availability in your country.

| | | | |
|---|---|---|---|
| **Headquarters** | **+33 1 41 45 07 10** | | |
| Australia | 1800 815 098 | New Zealand | 0800 555 611 |
| BELUX | +32 92 820 531 | Serbia | +381 11 2467119 |
| Brazil | +55 27 3025 1415 | The Netherlands | +31 313 430 581 |
| France | +33 4 83 36 10 82 | UK | +44 1442 869320 |
| Italy | +39 011 97 61 91 | United States | +1 800 453 2725 |

ELITechGroup
EMPOWERING IVD

**www.elitechgroup.com**
**info@elitechgroup.com**


6003-500-490-02 EN