

Anexa nr.4 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 automate destinate analizelor biochimice cu sistem deschis deschis de reactiv. | |
| Parametrul | Specificația solicitată | SPECIFICAȚII TEHNICE OFERTATE Selectra ProS (Elitech/Olanda) |
| Sistem analitic | Automat, cu calculator integrat sau exterior (procesor, monitor, tastatură+mouse). | Automatizat, cu calculator integrat (procesor, monitor, tastatură+mouse). |
| Tip de lucru | continuu | Continuu |
| Tip sistem | deschis | deschis |
| | random 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 | staționar | Da |
| Tip probă | Ser și plasmă | Ser și 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 cu răcire pentru menținerea probelor | cu termostat la 37 grade C | Da |
| Rotor cu încălzire pentru probe cu termostat la 37 grade C | DA | DA |
| Cuvă pentru probe reutilizabil, (indicați | da | Da, 10 000 cicluri |

| | | | |
|---|--|---------------------------------------|---------------------------------------|
| ciclurile posibile de reutilizare) | | | |
| Regimuri de măsurare: | | Cinetic | Cinetic |
| | | Mono și bi-cromatic | Mono si bi-cromatic |
| | | Imunoturbidimetric (Turbidity) | Imunoturbidimetric (Turbidity) |
| | | Controlul cantității de reagent rămas | Controlul cantității de reagent rămas |
| Semnalizare | | Lipsa reagent si proba | Da |
| 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 | 220 V, 50 Hz |

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T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 2145682

The management system of the organization(s) and/or location(s) of:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

Certified organization(s) and/or locations:

Different scope

ELITechGroup S.p.A.
Corso Italia 22
20122 Milano
Italy

Registered office without operational responsibilities

ELITechGroup S.p.A.
Corso Svizzera 185
10149 Torino
Italy

The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods.
The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods

Addendum expiry date: 7 January 2023

Addendum effective date: 31 January 2020

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



001

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. |



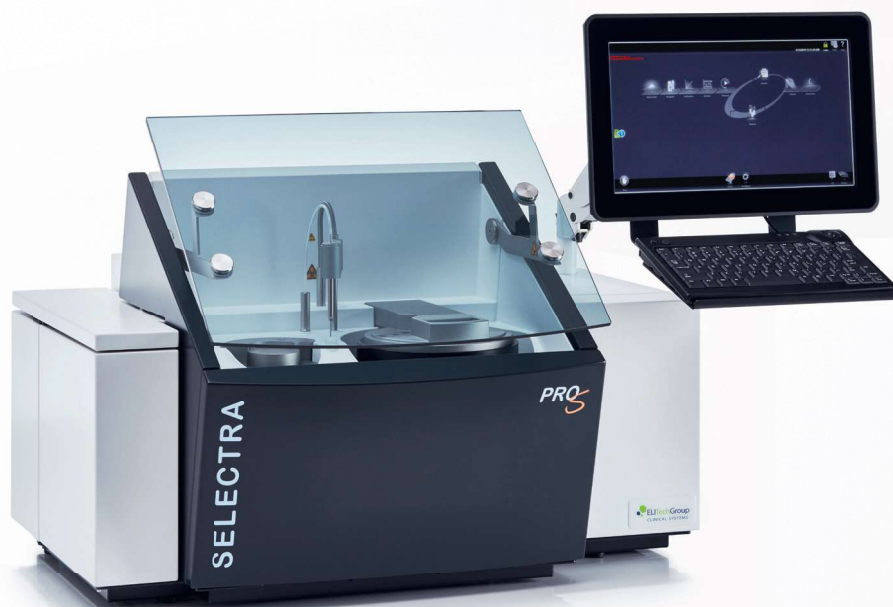
001



Clinical Systems

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FOR LABORATORIES
LOOKING TO AUTOMATE



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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:
 - 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
- 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 - MDD
- 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

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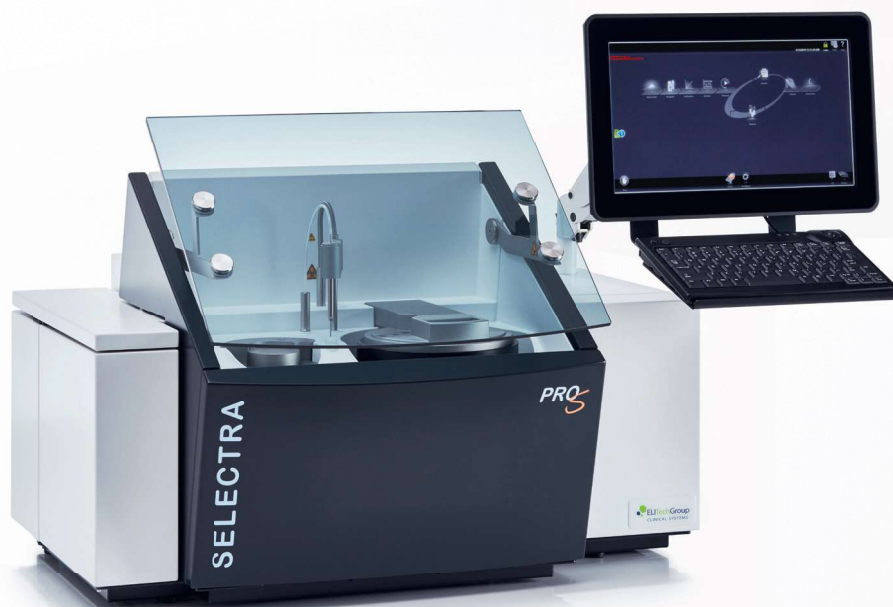
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