Anexa 1 la formularul Specificatii Tehnice Anexa 23

Lotul nr. 1 Analizator biochimic automat sistem inchis

Nr.	Denumire produs	Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi			Specificații tehnice oferite
	Analizator biochimic, automat sistem inchis	**Descriere**		Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi	Analizator automat destinat analizelor biochimie cu sistem inchis de reactivi, model Selectra Mach5 (Elitech/Olanda)
		Parametru		**Specificația**	
		Tip de lucru		continuu	continuu
		Tip sistem		inchis	inchis
				randoom acces	Random acces
		Capacitatea (teste/oră)		≥ 240 (teste fotometrice, fără modulul ISE)	250 tests fotomerice/hour pentru dual reagent tests 500 tests fotomerice/hour pentru mono-reagent tests
		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	≤1.6L	da
		Program control al calității	**Management intern al controlului calitatii**	da	da
			Posibilitatea programarii valorilor controalelor si calibraorilor la distanta	da	da
		Compartiment reactivi	**Cantitate maxima reactivi concomitent**	≥52	Da, de la 30 la 80

			Cantitate de reactivi concomitent	≥30	De la 30 la 80
			Capacitatea buteliilor cu reactivi	20ml si 50ml	10 mL, 30 mL si 90 mL reagent
			Detectia nivelului de lichid	da	da
			Consum de reagent poate fi programat	10µl - 440µl	Da, cu pas de 1 µL
		Compartiment probe	**Cantitate probe la bord**	≥72	90
			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 (increment de 0.1 µL)
		Rotor cu încălzire pentru probe	**cu termostat la 37 grade C**	da	Cu termostat la 37 grade C
			Cantitatea celulelor pentru reactie	≥120	128
			De o singura folosinta	da	>10,000 tests per rotor
			Volum de reactie	200 µL – 800 µL	110 to 400 µL
		Regimuri de măsurare	**cinetic**	da	da
			mono și bi-cromatic	da	da
			imunoturbidimetrc (Turbidity)	da	da
			Filtre optice utilizate	≥8	12
			Diapazonul filtrelor	340nm – 900nm	Da, 340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800nm
			Functie de detectie a proznei	da	da

		Sistem operational	**Calculator extern**	da	Calculator integrat, Windows 10 Enterprise LTSC; Touchscreen monitor 15.6 inch, 1366 x 768 pixels
			Interfata LIS	da	da
			Posibitatea conectarii la distanta	da	da
			Program intuitiv si usor de utilizat	da	da
		Sistem de dozare	**Sensor de obstacol**	da	da
			Volum de dozare	3 µL – 1250 µL	
			rezolutia	≤0.126 µL	0 to 3.0 Abs
			Viteza de dozare	≥880 µL/s	Da
		Lampa halogen		12 V, 20W	Da, Quartz-iodine lamp 12V-20W
		Monitorizare automata a duratei de lucru		da	da
		Alimantare		220V, 50Hz	100 - 240 Vac ±10%; 50/60Hz
		Greutate		≤73 kg	110kg
		CE		Certificate/declaratie	Declaratie de Conformitate
		ISO 13485		DA	DA
		ISO 9001		DA	DA
		Inginer autorizat de producator		Da	Da

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5. Make Work Flow

14/01/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5: Basic Application Specialist Training

14/01/2022
Issued date

Maurice Verdaasdonk
Vice President Clinical Systems

ELITechGroup
EMPOWERING IVD

Clinical Systems

CERTIFICATE

Sergiu Sorocovici

has successfully completed the

Selectra Mach5: Basic Troubleshoot Training

03/04/2022
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						
DM000306836	ANALIZATOR BIOCHIMIC AUTOMAT		SELECTRA MACH5	6004-301	Olanda	ELITECHGROUP B.V.	GBG-MLD S.R.L.	Rg04-000110	17-05-2021

EU Declaration of Conformity

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

declares under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of:

- Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *In vitro* diagnostics medical devices ("IVD Regulation")
- 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"), 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 ("RoHS3").

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

Catalogue number	Description	GTIN
6004-301	Selectra Mach5	0 3661540 60054 8

Product	**Multiple clinical chemistry analyzer IVD, laboratory, automated**
SRN	**TBD**
Risk Class	**A**
GMDN code	**56676**
Accessories	**See Annex**

Product classification
As per Article 48, section 10 the products are categorized as class A device ("self-declaration").

Conformity assessment procedure
In accordance with:

- Article 18 of the IVD Regulation
- Article 4 of the RoHS2 Directive

Spankeren, January 2021

M.A.S.V.E. Verdaasdonk
Managing Director

EU Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010, AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	UL
	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 61010-2-051:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring.	
	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	
	UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1. General requirements	UL
EMC	IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2012	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

Annex – List of IVD accessories

Catalogue number	Description	GTIN
3201-019	Precision Test Solution	0 3661540 60042 5
6004-338	Drying Block Set	0 3661540 60470 6
6004-351	Cuvette rotor set (3 pieces)	0 3661540 60043 2

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

MACH 5

Make work flow

ELITechGroup

EMPOWERING IVD

Selectra **Mach®5**

An innovative benchtop solution to match your laboratory's needs now and into the future

- Quality and sturdiness – synonymous with the Selectra brand
- Maximum efficiency through consolidation of routine and special testing
- The accuracy required to help clinicians provide the best patient outcomes
- Economical benchtop solution

Now, how can Selectra Mach®5 add additional value for your clinical chemistry laboratory?

Choose your next benchtop system wisely

When choosing the right solution for your clinical chemistry laboratory, features that directly impact your laboratory's productivity will be critically important.

You will look for the best option to complete your workload with the existing or even less resources.

Simply making side by side comparisons of published technical specifications does not provide the critical information for your unique situation.

An integrated approach, that combines the critical productivity elements in a benchtop system, provides the additional insight required to make your work flow.

An integrated approach to benchtop system efficiency: The Benchtop System Workflow Index™

Efficient workflow depends on much more than a system's published specifications

Benchtop System Workflow (BSW) Index is a different way to compare the overall efficiency of benchtop systems using published specifications

The higher the BSW Index™, the more efficient the workflow in your laboratory

$$\frac{\text{SAMPLE CAPACITY \%}^{1} \times \text{ONBOARD MENU CAPACITY \%}^{2} \times \text{TPH}_{CALC}{}^{3}}{100} = \textbf{BSW INDEX}$$

1 Sample Tray Capacity divided by the capacity needed to perform your daily workload.

2 Onboard Menu Capacity divided by the capacity needed to load your complete routine test menu.

3 Calculated theoretical Tests Per Hour performing your typical daily workload.

How the BSW Index works

The BSW Index assesses the overall workflow in a lab by incorporating three productivity elements of the benchtop system.

In short, it is a measure of benchtop speed ("calculated Tests Per Hour") combined with measurements of benchtop-staff interactions during instrument operating time.

The higher the BSW Index, the more efficient the workflow in your laboratory

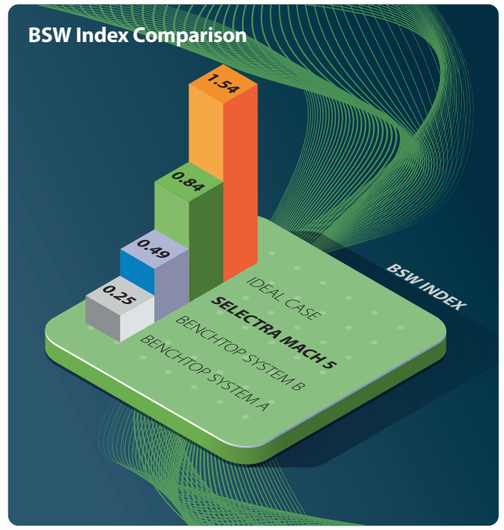
Let's look at the following scenario:

A routine clinical chemistry laboratory needs a new benchtop clinical chemistry system. Demand is expected to grow to 300 samples/day, requiring a menu of 40 parameters[3], with an average of 12 tests/sample. The laboratory is operational 12 hours/day.

A "top 3" of benchtop systems is selected, based on published specifications meeting the current and future productivity needs: Selectra Mach5, Benchtop system A and Benchtop system B.

To determine which system will be most efficient, the BSW Index for all 3 systems is calculated.

Conclusion: for this laboratory, the Selectra Mach5 would be the best fit.



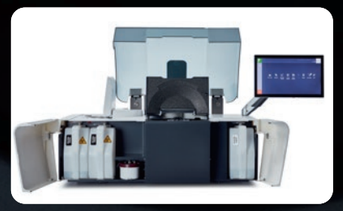
The values for the Ideal Case and the 3 selected instruments are displayed in the table below:

Top 3 selected Benchtop Systems:	SELECTRA MACH5	SYSTEM A	SYSTEM B	IDEAL CASE[1]
SAMPLE CAPACITY	83	40	50	110 (C[2])
ON BOARD REAGENT CAPACITY[3]	68	50	100	100 (B)
CALCULATED TPH (based on cycle time values)	314	270	216	300
BSW INDEX	0.84	0.25	0.49	1.54

1. The Ideal Case is calculated by selecting the maximum score for each efficiency element, from all the instruments used in the comparison, and the desired throughput (in this case 300 Tests Per Hour).
2. Instrument C has the most optimal sample capacity but, because of insufficient throughput, did not make the short list.
3. Reagent positions required for the selected menu for non-ELITech Systems are based on publicly available information. For the Selectra Mach5, 70 reagent positions are required for the selected test menu.

Make work flow with Selectra Mach®5. A new approach to benchtop system efficiency

Other key features of the Selectra Mach®5



System completeness: Unlike many other systems, Selectra Mach®5 has everything included in the system, minimizing footprint. A built-in computer system including touchscreen monitor enabling better cyber security. An integrated supply of system liquid, simplifying system handling for the operator, or, in other words, optimizing human-system interventions.

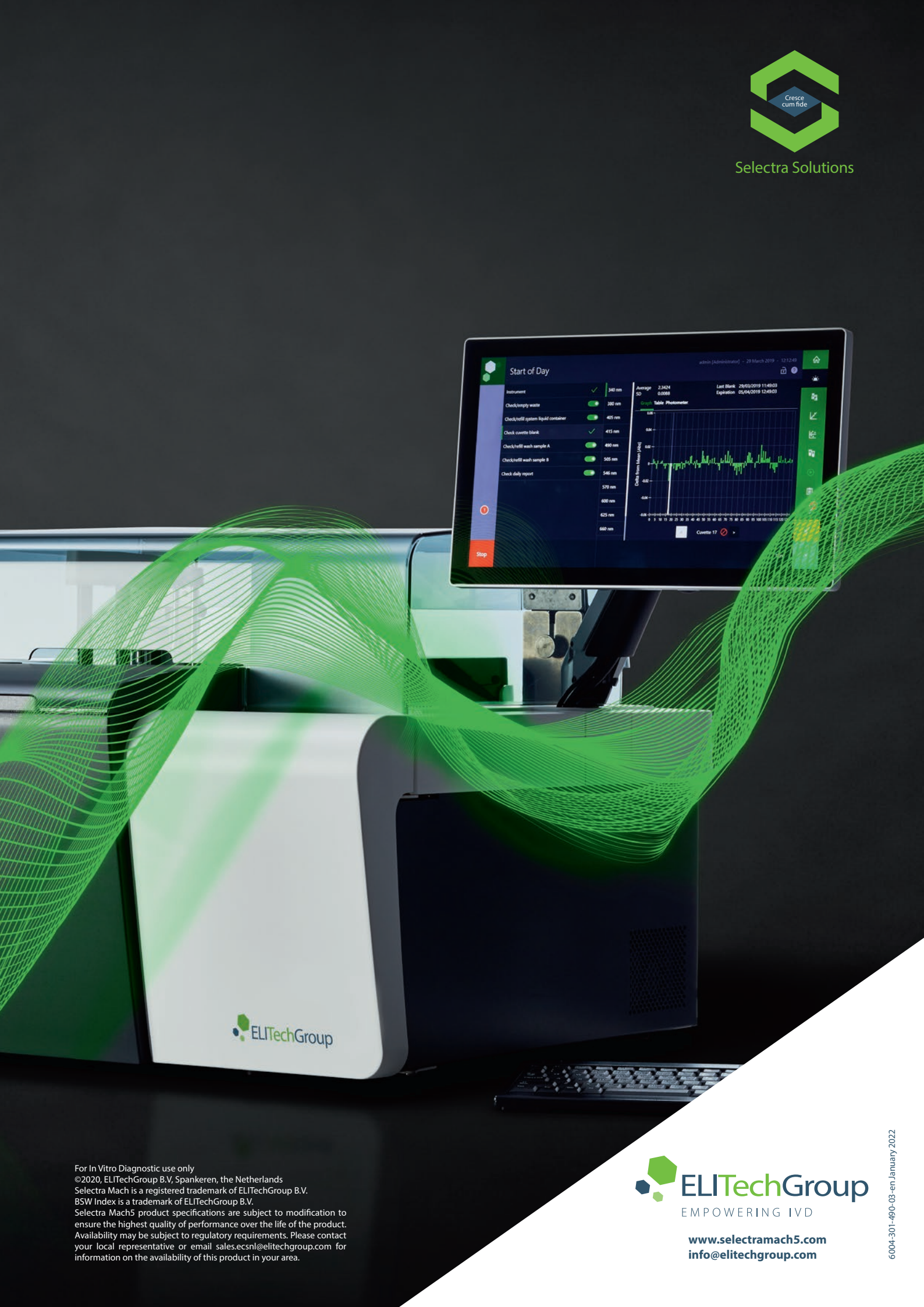
Water usage: Selectra Mach5 has an onboard water capacity of 10L and typically uses up to 2.5L/h. The system is designed to perform efficiently, therefore both the water and waste containers can be replaced without interrupting the analytical process.

Photometric module: The unique photometers of Selectra Mach5 are LED-based and have a significantly longer life span than the halogen lamp in lamp-based photometers used in many other clinical chemistry systems. Moreover, the LED photometric cartridge technology provides more flexibility and adaptability for future assay developments, as up to 16 individual LED photometer cartridges with a specific wavelength can be accommodated (12 included as standard).

GENERAL SPECIFICATIONS

INSTRUMENTS	
SYSTEM	Fully automated, random access, benchtop clinical chemistry system with STAT capability
COUNTRY OF ORIGIN	Netherlands
DIMENSIONS	105 cm (w) x 70 cm (d) x 65 cm (h)
WEIGHT	110 Kg
OPERATING ENVIRONMENT	Between 15-32 °C; 30-85 % relative humidity (non condensing); and up to 3,000 m above sea level
INTEGRATED PLATFORM	Instrument with inbuilt PC, software, reagents, calibrators, controls and consumables
ANALYSIS MODES	Quantitative, Semi-Quantitative and Qualitative
ASSAY TYPES	Quantitative Kinetic Rate, Fixed Point Rate, End Point; Semi-quantitative; and Qualitative (cut-off)
ASSAY TECHNOLOGIES	Colorimetric (UV-Visible spectra), Turbidimetric
TEST MENU	
PROGRAMMABLE TESTS	1,000
ON BOARD REAGENT CAPACITY	Up to 65 Bar Code Readable (BCR) positions, cooled at 8 ± 4 °C
ON BOARD TEST CAPACITY	At least 39 Parameters when using ELITechGroup system reagents
SYSTEM REAGENT MENU	At least 40 CE marked system reagents
USE OF THIRD PARTY REAGENTS	Yes, capability of running third party assays not available from ELITechGroup
WORK FLOW	
PRIMARY TUBE SAMPLING	Primary- tube diameter ranging from 12 to 16 mm and a height ranging from 75 to 100 mm
CONTINUOUS REAGENT AND SAMPLE LOADING	Yes, samples and reagents, via dedicated sample and reagent access covers (maximum pause time for sample of 2 minutes)
ON BOARD SAMPLE CAPACITY	85 sample positions. 65 BCR and 20 auxiliary positions (inner ring)
THROUGHPUT RANGE (PHOTOMETRICS)	250 to 500 photometric TPH
THROUGHPUT /M²	340 to 680 photometric TPH/m^2
TIME TO FIRST RESULT (PHOTOMETRICS)	< 5 minutes when using ELITech system reagents (assay dependent)
STAT LOADING	Utilising pause function, so no interruption to tests already in progress
AUTOMATIC REPEAT TESTING	Yes, automatic onboard dilution of out of range results
WALK AWAY TIME	Up to 4 hours using ELITechGroup system reagents
VALIDATED SAMPLE TYPES	Serum, Plasma, Whole Blood and Urine (assay dependent)
SAMPLE INTEGRITY	Sample clot detection
SAMPLE AND REAGENT IDENTIFICATION	Inbuilt BCR for risk free loading of samples and reagents
SYSTEM CONTROL	
OPERATING SYSTEM	Windows 10 based operating system
USER COMMANDS	15.6 inch capacitance Touch and Swipe screen, resolution 1366 x 768 pixels and widescreen (16:9) aspect ratio
APPLICATIONS	Automatically downloaded from 2D barcode on IFU with handheld BCR
CONTROL AND CALIBRATOR DATA	Automatically downloaded from 2D barcode on IFU with handheld BCR
STATUS DISPLAY	Instrument status, time for completion are displayed in real time
START UP PROCEDURE	System can be programmed for automated start up outside routine hours to prevent interruptions to workflow
SHUT DOWN PROCEDURE	System can be programmed for automated shut down outside routine hours to prevent interruptions to workflow
STORAGE CAPACITY	256 GB solid state hard disk
OPERATOR SAFETY	
ACCESS WHEN OPERATING	Cover open /closed detection. Transparent instrument cover, so moveable parts are visible during operation
MAIN COVER	Open/Closed detection
SAMPLE COVER	Open/Closed detection
REAGENT COVER	Open/Closed detection
CUVETTE ROTOR COVER	Open/Closed detection
NOISE EMISSION	Balanced noise criterium at NCB-58; Sound pressure 58 dB(A)max. when in use
REGULATORY COMPLIANCE	
IVD MEDICAL DEVICES	CE-marked in accordance with EU IVD Regulation 2017/746
ROHS	CE-marked in accordance with EU Directive 2011/65/EU
SAFETY	Tested and certified according to: IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015, IEC 61010-2-101:2015
ELECTROMAGNETIC COMPATIBILITY	Tested and certified by DEKRA according to: IEC 61326-1:2012, IEC 61326-2-6:2012

CE



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