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SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

1137048

Din
От

08.12.2025 11:37



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Digitally signed by Poiata Vitalie

Date: 2025.12.15 15:39:14 EET

Reason: MoldSign Signature

Location: Moldova



Denumirea

Наименование

BIOSISTEM MLD



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI

INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ

ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

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VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

23.12.2025 11:37



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 08.12.2025 11:37

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are același valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью (msign.gov.md)

Optimization and flexibility

BioSystems

A15 Clinical Chemistry Analyser

Clinical analysis

human - centred biotech



We have come a long way
to provide a simple solution
for laboratory automation.





Building usability



Efficiency in lab Automation

A15 is a small size and low demanding analyser that facilitates automation of tests, reducing working time and improving the laboratory efficiency.



Easy to handle and flexible system

Its low maintenance and an easy to use software make A15 a very adaptable system, contributing to solve user needs.



Reliable validated system

Dedicated and validated reagents ensure a robust and reliable analytical system.



Durability over time

With a long history on the market, we still find new niches or applications to explore.



Systemic solutions

A long history of collaboration with users to improve this analyser, together with a complete panel of clinical chemistry reagents, make A15 system a perfect option for different size laboratories. It adapts to user needs in laboratories implementing their first automated system, in laboratories looking for dedicated special tests analysers or any other segment.

With more that 8000 analysers worldwide, we can offer a wide experience in Customer Support, not only responding to users requests but also developing new reagents and solutions validated under the same european brand.

Our main focus is to satisfy our users requirements and strive to exceed their technical, economical and human expectations. We are committed to provide the best possible user experience.



Scientific
& Technical
Support



Remote
Assistance



Personalised
Support

Technical Specifications

Highlights

- Optimal onboard capacity for refrigerated and non-refrigerated reagents.
- High flexibility for positioning different sample and reagents containers.
- Optimal reagent standardization for effective use of consumables.
- Intuitive system with seamless connection to LIS.
- Up to 150 tests per hour.
- Filter configuration adapted to all biochemistry reactions (340, 405, 505, 535, 560, 600, 635, 670 nm +1 additional filter can be added by user).
- Consistent prozone detection function.
- Reduced reaction volume up to 180 μ L.
- Open user configuration of test parameters.
- Repetition with automatic pre-dilution and post-dilution possibilities.
- Sustainable design with low water consumption (less than 0.5 L/hour).

Ordering Information

Item	Code	Quantity
A15 analyser	83105	-
A15C analyser, with cooling system for 20 refrigerated reagents positions	83105C	-
Concentrated system liquid	BO11524	1000 mL
Concentrated washing solution	BO13416	100 mL
Reaction rotor	AC11485	10 units
Sample wells (pediatric cups)	AC10770	1000 units
Reagent bottles 50 mL + caps	BO11493	10 units
Reagent bottles 20 mL + caps	BO11494	10 units
Amber reagent bottles 50 mL + caps	BO13442	10 units



Throughputs	
Throughput	150 t/h
Sample handling	
Positions for racks (reagents or samples)	4 (reagents or samples) or 2 in A15C
Rack samples capacity	24 sample positions/rack
Maximum capacity of samples	72 or 48 in A15C
Barcode reader	External
Size of primary tubes	Size of primary tubes Ø 13 mm or 15 mm (max. height 100 mm)
Sample well Diameter	13 mm
Sample types	Serum, plasma, urine, whole blood, cerebrospinal liquid, semen and biological fluids
Dispensing pump	Ceramic pump of high durability
Dispensing tip	Stainless Steel 110 mm
Level detection	Capacitive
Sample pipetting volume	From 2 µL to 80 µL
Pipetting resolution	0.1 µL
Predilution ratio	From 1:2 to 1:200
Clot detector	No
Tip wash	Inside and outside
Reagent handling	
Volume of reagent bottles	20 mL, 50 mL
Number of reagents per reagent rack	10 bottles of 20 or 50 mL
Cooled reagent	Yes in A15C. 20 reagents max.
Temperature range of refrigerator	10°C below room temperature (at 25°C)
R1 volume	10 µL to 550 µL
R2 volume	10 µL to 200 µL
Dispensing mode	Ceramic pump without maintenance
Pipetting resolution	1 µL
Tip wash	Inside and outside
Reactions rotor	
Reaction volume range	From 180 µL to 800 µL
Number of wells	120
Well material	UV methacrylate
Type of incubation	Dry without maintenance
Temperature	37.0 °C
Temperature accuracy	±0.2 °C
Optical System	
Light Source	Halogen lamp (6V, 10W)
Lightpath	6 mm
Wavelengths	340 - 405 - 505 - 535 - 560 - 600 - 635 - 670 nm (+1 additional filter can be added by user)
Wavelength accuracy	±2 nm
Spectral range	340 - 900 nm
Photometric range	-0.05 to 3.0 A
Photometric detection system	Silicon photodiode
Internal resolution	<0.0001 A
Baseline stability	Max. 0.004 A, 30 minutes at 505 nm
Size and weight	
Size (w., d., h.)	815 x 665 x 600 mm
Weight	45 Kg
Electrical and Environmental Requirements	
Mains voltage	115 to 230 V
Mains frequency	50 or 60 Hz
Electric power	150 VA (200 VA A15C)
Ambient temperature	From 10 to 35°C
Relative humidity	<75%
Altitude	<2500 m
Fluidic Requirements	
System liquid solution bottle volume	3 L
Washing solution bottle volume	3 L
Waste solution bottle volume	3 L
Minimum Computer Requirements	
Operating system	Windows® 10 64 bit (x64)
CPU	Equivalent to Intel Core i3 @3.10 GHz or higher
RAM	512 MB
Hard Disk	20 GB or higher
Monitor minimum resolution	800x600
Connector of serial channel	USB
Laboratory Information Systems (LIS)	
Connectivity to LIS	Yes
Regulatory Compliance	
IVD - CE	Regulation (EU) 2017/746



A15

Reagents

Test	Code	RA	RB	mL/Kit	Comments
α-AMYLASE DIRECT <i>Alpha-GLUCOSIDASE</i>	12522	2 x 20 mL	2 x 5 mL	50	Std Inc
α-AMYLASE-EPS <i>IFCC</i>	12535	1 x 32 mL	1 x 8 mL	40	WR
α-AMYLASE PANCREATIC <i>Immunoinhibition</i>	12799	1 x 40 mL	1 x 10 mL	50	
α-GLUCOSIDASE NEW <i>Glucose oxidase/Peroxidase</i>	12522	2 x 20 mL	2 x 5 mL	50	Std Inc
ADENOSINE DEAMINASE (ADA) <i>Adenosine-Glutamate Dehydrogenase</i>	12754	4 x 8 mL	1 x 10 mL	40	WR
ALANINE AMINOTRANSFERASE (ALT/GPT) <i>IFCC</i>	12533	5 x 40 mL	5 x 10 mL	250	WR
ALBUMIN <i>Bromocresol Green</i>	12547	5 x 50 mL	-	250	
ALBUMIN (MICROALBUMINURIA) <i>Latex</i>	13324	1 x 40 mL	1 x 10 mL	50	WR
ALKALINE PHOSPHATASE (ALP)-AMP <i>AMP Buffer (IFCC)</i>	12518	5 x 16 mL	2 x 10 mL	100	WR
ALKALINE PHOSPHATASE (ALP)-DEA <i>DEA Buffer</i>	12514	5 x 16 mL	2 x 10 mL	100	WR
AMMONIA <i>Glutamate Dehydrogenase</i>	12532	1 x 20 mL	1 x 7 mL	27	RA
ANGIOTENSIN CONVERTING ENZYME (ACE) <i>FAPGG</i>	12796	1 x 50 mL	-	50	
ANTI-STREPTOLYSIN O (ASO) <i>Latex</i>	13923	1 x 40 mL	1 x 10 mL	50	WR
ASPARTATE AMINOTRANSFERASE (AST/GOT) <i>IFCC</i>	12531	5 x 40 mL	5 x 10 mL	250	WR
β-HYDROXYBUTYRATE <i>Hydroxybutyrate Dehydrogenase/Diaphorase</i>	12525	1 x 40 mL	1 x 10 mL	50	
BILIRUBIN (DIRECT) DPD <i>Dichlorophenyl Diazonium</i>	12504	5 x 40 mL	5 x 10 mL	250	
BILIRUBIN (TOTAL) DPD <i>Dichlorophenyl Diazonium</i>	12506	5 x 40 mL	5 x 10 mL	250	
CALCIUM-ARSENAZO <i>Arsenazo III</i>	12570	10 x 50 mL	-	500	

WR: Working Reagent / **RA:** Reagent A Preparation / **RB:** Reagent B Preparation / **Std Inc:** Standard Included

Test	Code	RA	RB	mL/Kit	Comments
CALCIUM-CRESOLPHTHALEIN <i>O-Cresolphthalein Complexone</i>	12513	5 x 40 mL	5 x 10 mL	250	
CARBON DIOXIDE (CO₂) <i>Phosphoenolpyruvate Carboxylase/Malate Dehydrogenase</i>	11558	1 x 50 mL	-	50	
CERULOPLASMIN NEW <i>Turbidimetry</i>	13340	1 x 40 mL	1 x 10 mL	50	
CHOLESTEROL LDL DIRECT [TOOS] NEW <i>Direct TOOS</i>	12785	3 x 20 mL	1 x 20 mL	80	
CHOLESTEROL HDL DIRECT [TOOS] NEW <i>Direct TOOS</i>	12757	3 x 20 mL	1 x 20 mL	80	
CITRATE <i>Citrate Lyase/ Malate Dehydrogenase</i>	11895 11795	1 x 20 mL 2 x 20 mL	1 x 5 mL 2 x 5 mL	25 50	RB + Std Inc RB + Std Inc
COMPLEMENT COMPONENT C3 <i>Turbidimetry</i>	13084	1 x 50 mL	-	50	
COMPLEMENT COMPONENT C4 <i>Turbidimetry</i>	13085	1 x 50 mL	-	50	
C-REACTIVE PROTEIN (CRP) <i>Latex</i>	13921	2 x 40 mL	2 x 10 mL	100	WR
C-REACTIVE PROTEIN hs (CRP-hs) <i>Immunoturbidimetric latex assay, High Sensitivity</i>	13927	1 x 40 mL	1 x 10 mL	50	WR
CREATINE KINASE (CK) <i>IFCC</i>	12524	3 x 12 mL	1 x 10 mL	45	WR
CREATINE KINASE-MB (CK-MB) <i>Immunoinhibition</i>	12566	3 x 12 mL	1 x 10 mL	45	WR
CREATININE <i>Jaffé-compensated</i>	12502	5 x 50 mL	5 x 50 mL	500	WR
CREATININE ENZYMATIC <i>Enzymatic</i>	12734	1 x 45 mL	1 x 15 mL	60	
ETHANOL <i>Alcohol Dehydrogenase</i>	12789	1 x 20 mL	1 x 7 mL	27	
FERRITIN <i>Latex</i>	13934	1 x 30 mL	1 x 15 mL	45	WR
FIBRINOGEN <i>Turbidimetry</i>	13600	1 x 40 mL	1 x 10 mL	50	
FRUCTOSE <i>Hexokinase/ Phosphoglucose Isomerase</i>	11794	1 x 40 mL	1 x 10 mL	50	Std Inc, WR
γ-GLUTAMYL TRANSFERASE (γ-GT) <i>IFCC</i>	12520	5 x 40 mL	5 x 10 mL	250	WR
GLUCOSE <i>Glucose Oxidase/ Peroxidase</i>	12503	10 x 50 mL	-	500	
GLUCOSE-6-PHOSPHATE DEHYDROGENASE NEW <i>Glucose-6-Phosphate</i>	12603	1 x 40 mL	1 x 10 mL	50	Std Inc

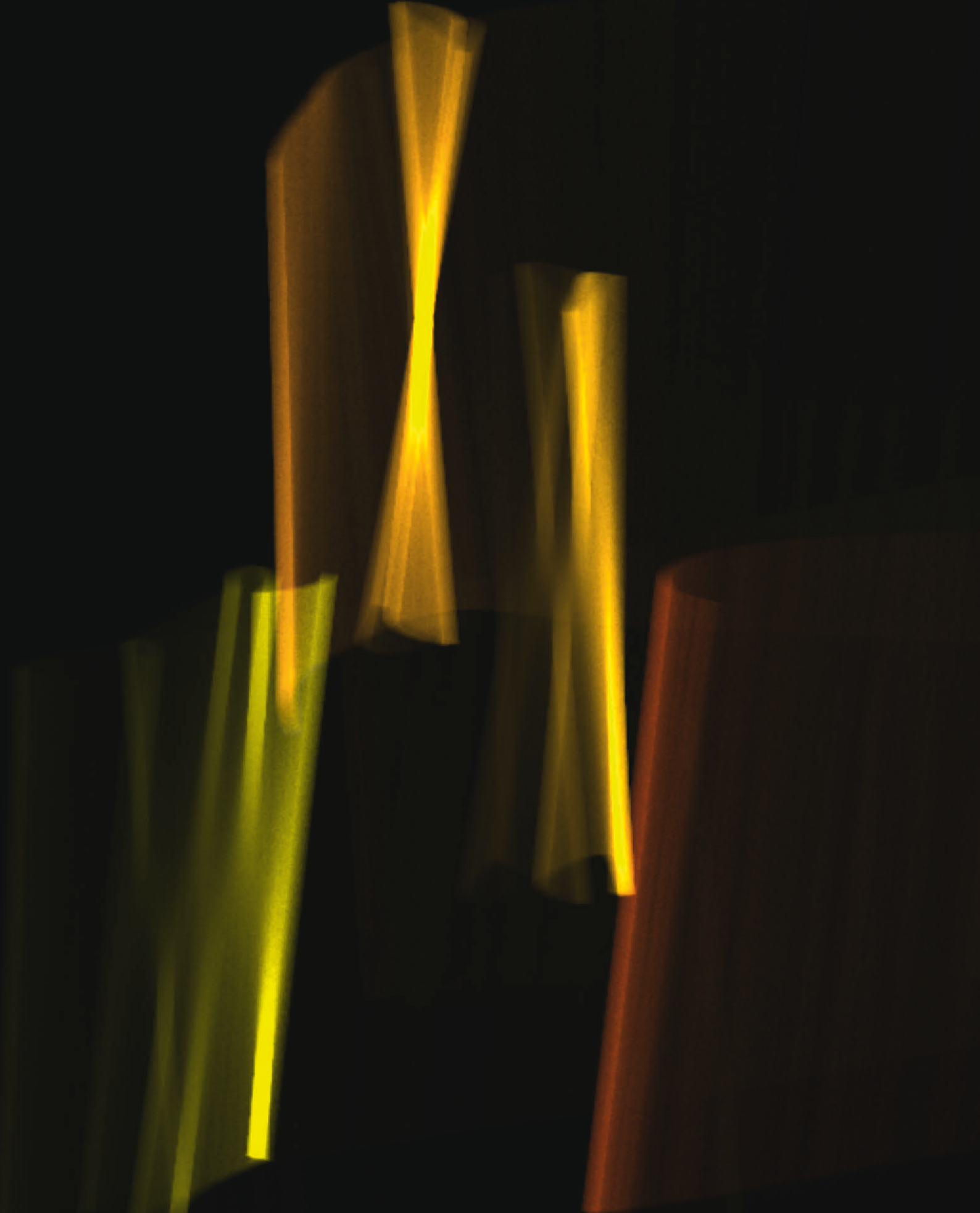
WR: Working Reagent / RA: Reagent A Preparation / RB: Reagent B Preparation / Std Inc: Standard Included

Test	Code	RA	RB	mL/Kit	Comments
GLUCOSE-HEXOKINASE <i>Hexokinase</i>	12756	2 x 40 mL	2 x 10 mL	100	
HAPTOGLOBIN NEW <i>Turbidimetry</i>	13218	1 x 40 mL	1 x 10 mL	50	
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) <i>Latex</i>	13047	1 x 50 mL	1 x 10 mL	60	
HOMOCYSTEINE <i>Enzymatic Cycling</i>	12737	1 x 40 mL	1 x 10.8 mL	50.8	
IMMUNOGLOBULIN A (IgA) <i>Turbidimetry</i>	13082	1 x 50 mL	-	50	
IMMUNOGLOBULIN G (IgG) <i>Turbidimetry</i>	13081	1 x 50 mL	-	50	
IMMUNOGLOBULIN M (IgM) <i>Turbidimetry</i>	13083	1 x 50 mL	-	50	
IRON-FERROZINE <i>Ferrozine</i>	12509	5 x 40 mL	5 x 10 mL	250	
LACTATE <i>Lactate Oxidase/ Peroxidase</i>	12736	2 x 40 mL	2 x 10 mL	100	
LACTATE DEHYDROGENASE (LDH) <i>Pyruvate</i>	12580	5 x 40 mL	5 x 10 mL	250	WR
LACTATE DEHYDROGENASE (LDH)-IFCC <i>IFCC</i>	11586	1 x 40 mL	1 x 10 mL	50	WR
LIPASE NEW <i>DGGR</i>	12760	1 x 20 mL	1 x 10 mL	30	
MAGNESIUM <i>Xylidyl Blue</i>	12797 23797	5 x 16 mL 1 x 60 mL	2 x 10 mL 1 x 15 mL	100 75	WR
NON-ESTERIFIED FATTY ACIDS (NEFA) NEW <i>Acyl-CoA Oxidase/Peroxidase</i>	12540	2 x 20 mL	2 x 7 mL	54	RA, RB
OXALATE <i>Oxalate Oxidase/Peroxidase</i>	12539	1 x 20 mL	1 x 5 mL	1 x 25 mL R1 + 20 tubes (pretreatment reagent)	Std Inc, RB
PHOSPHORUS <i>Phosphomolybdate/UV</i>	12508	3 x 24 mL	2 x 15 mL	100	
PROTEIN (TOTAL) <i>Biuret</i>	12500	10 x 50 mL	-	500	
PROTEIN (URINE+CSF) <i>Pyrogallol Red</i>	12501	5 x 50 mL	-	250	Std Inc
RHEUMATOID FACTORS (RF) <i>Latex</i>	13922	1 x 40 mL	1 x 10 mL	50	

Test	Code	RA	RB	mL/Kit	Comments
TOTAL BILE ACIDS <i>Enzymatic Cycling</i>	12551	1 x 18 mL	1 x 6 mL	24	Std Inc
TRANSFERRIN <i>Turbidimetry</i>	13091	1 x 50 mL	-	50	
TRIGLYCERIDES <i>Glycerol Phosphate Oxidase/Peroxidase</i>	12528	10 x 50 mL	-	500	
UNSATURATED IRON BINDING CAPACITY (UIBC) <i>Ferrozine</i>	12835	1 x 40 mL	1 x 10 mL	50	
UREA/ BUN-UV <i>Urease/ Glutamate Dehydrogenase</i>	12516	5 x 40 mL	5 x 10 mL	250	WR
URIC ACID <i>Uricase/Peroxidase</i>	12521	10 x 50 mL	-	500	
ZINC <i>Bromo-PAPS</i>	12526	2 x 20 mL	1 x 10 mL	50	Std Inc, RA
PROTEIN (URINE+CSF) <i>Pyrogallol Red</i>	12501	5 x 50 mL	-	250	Std Inc
RHEUMATOID FACTORS (RF) <i>Latex</i>	13922	1 x 40 mL	1 x 10 mL	50	
TOTAL BILE ACIDS <i>Enzymatic Cycling</i>	12551	1 x 18 mL	1 x 6 mL	24	Std Inc
TRANSFERRIN <i>Turbidimetry</i>	13091	1 x 50 mL	-	50	
TRIGLYCERIDES <i>Glycerol Phosphate Oxidase/Peroxidase</i>	12528	10 x 50 mL	-	500	
UNSATURATED IRON BINDING CAPACITY (UIBC) <i>Ferrozine</i>	12835	1 x 40 mL	1 x 10 mL	50	
UREA/ BUN-UV <i>Urease/ Glutamate Dehydrogenase</i>	12516	5 x 40 mL	5 x 10 mL	250	WR
URIC ACID <i>Uricase/Peroxidase</i>	12521	10 x 50 mL	-	500	
ZINC <i>Bromo-PAPS</i>	12526	2 x 20 mL	1 x 10 mL	50	Std Inc, RA

A15 system:
a partner you can
depend on





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Management
System
ISO 9001:2015
ISO 13485:2016
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ID 0091006696

BC-5150

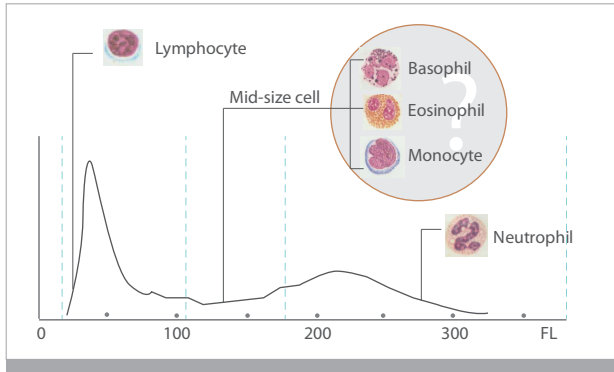
Auto Hematology Analyzer

A "CUTE" 5-part



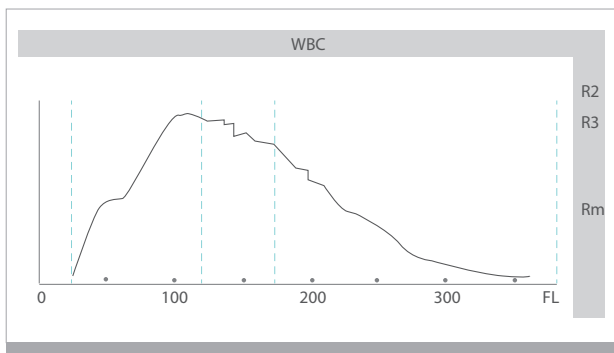
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



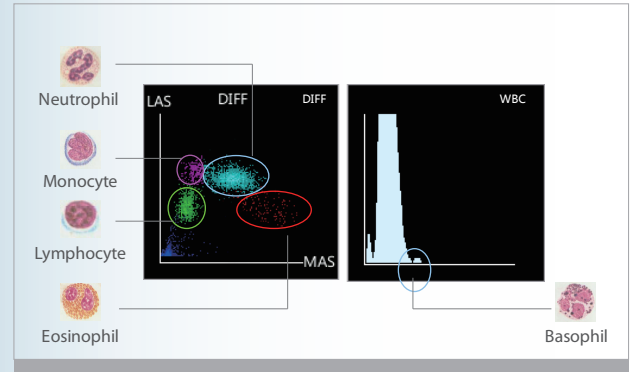
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

Flag information: 3-part



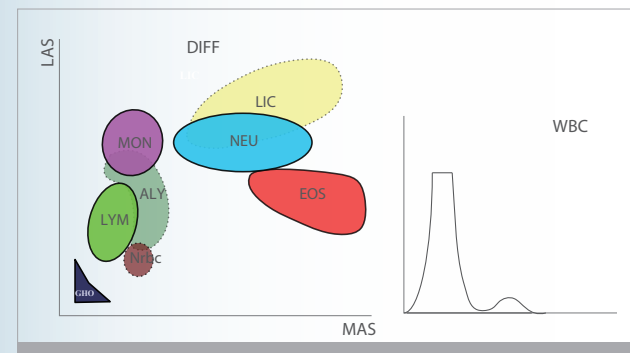
WBC histogram only indicates regional abnormal graph, it can't bring specific flags for different clinical cases.

WBC differential: 5-part



5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

Flag information: 5-part



5-part hematology analyzers provide more detailed and specific flag information. Users are able to clearly understand the clinical significance of flags and make a decision.



Dr Marisela Ramos, lab manager

Users are able to access our tailored innovation and intelligent diagnosis support to safeguard their diagnoses decisions with maximum confidence.

She said: "we upgraded to a 5-part hematology analyzer 3 months ago, and it's been working very well. Our lab has lots of abnormal samples, such as Eosinophilia and Monocytosis samples. We could only get the information that the mid-size cells percentage was higher than normal level, but couldn't distinguish which kind of cells increased exactly. Now, the 5-part hematology analyzer provides flags directly, which reduces smears need to be reviewed, and significantly improves our work efficiency."

BC-5150

Auto Hematology Analyzer

Based on Mindray's continuous innovation in hematology field, BC-5150 is especially tailored to assist diagnostic labs who need full CBC + 5-part results, with relatively low daily sample volume, restricted lab space and tight budget.

As the lightest and most compact 5-part hematology analyzer so far from Mindray, BC-5150 is a highly user-friendly and innovative analyzer that offers cost efficient CBC and 5-part white cell differential results. It is targeted to fulfill and exceed the demands of our global customers by providing more accurate, more efficient and more innovative solutions for labs.

WBC 5-part differentiation, 25 reportable parameters and 24 research parameters, 3 histograms and 4 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

Tri-angle Laser scatter + Chemical dye + Flow cytometry technology

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

10.4 inch large TFT touch screen with user-friendly software

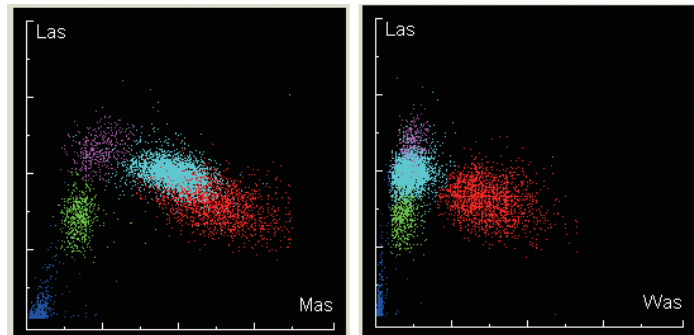
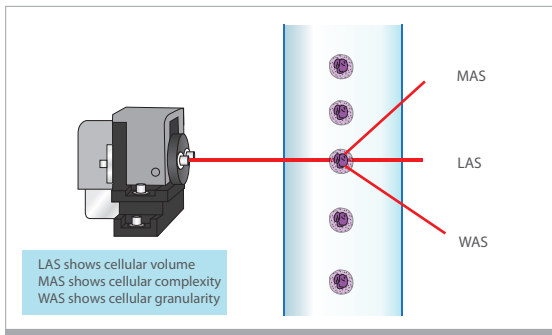
Large storage capacity: up to 250,000 samples

Throughput: 60 samples per hour

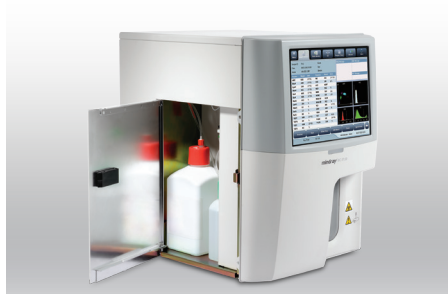
Sample volume is only 15 μ L which is ideal for pediatrics



Tri-angle laser scatter + focused flow + chemical dye, creating the possibility for a better 5-part WBC differentiation even on samples with high Eosinophil.



BC-5150, the 5-part hematology analyzer offers a great solution for clinical labs, especially for those who have limited space. Its compact foot-print is a result of innovative technology improvements, including miniaturized semi-conductor laser source, highly integrated electronic boards and optimized liquid handling system.



Compact

Two kinds of lyse reagents are located inside of BC-5150, which helps the small labs to save space.



Utility

The 10.4 inch TFT touch screen with a wide viewing angle, brings convenience to clinicians. Users can complete all instrument operations on the screen, practically eliminating the need for an external PC.



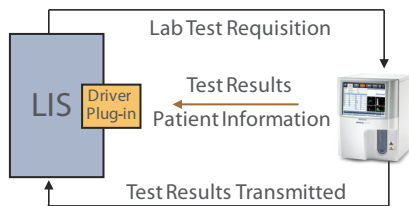
BC-5150 inherits its convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.



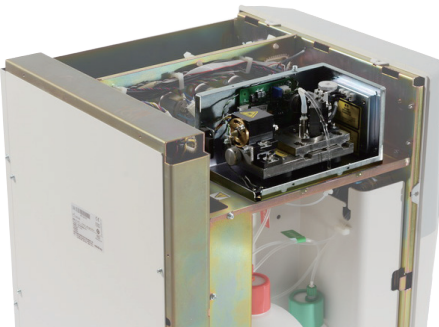
Running capillary blood through the sample probe directly is more convenient for the users in children's hospitals, etc. For Prediluted mode, BC-5150 has higher dilution ratio than other 5-part hematology analyzers, thus it brings a better mixing effect.



4 USB ports are located on the instrument's left side. They permit BC-5150 users to transmit data conveniently and connect with printers, keyboard, mouse, barcode scanner, etc.

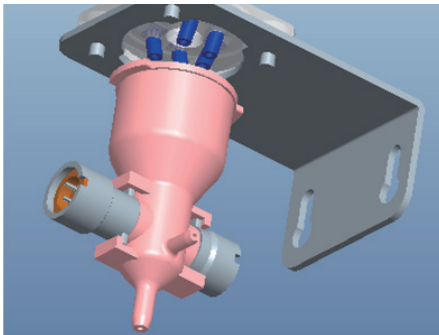


BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.



Technology

Compared with traditional helium neon laser or argon laser, semi-conductor laser has smaller size, lower cost and longer life cycle.



Improved DC impedance technology is used to count and size the RBC and PLT. The smaller counting aperture (50 μm in diameter) provides better performance on samples with low PLT.



Efficient

Only three routine reagents are required. These have 2 years shelf life and also less consumed by BC-5150. Original QC and calibrator are also provided to ensure the hematology analyzer's traceability and testing quality.

Technical Specifications

Principles

Impedance method for RBC and PLT counting

Cyanide free reagent for hemoglobin test

Flow Cytometry (FCM) + Tri-angle laser scatter + Chemical dye method for WBC 5-part differential analysis and WBC counting

Parameters

25 parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.

24 research parameters including LIC%, LIC#, ALY%, ALY#, PLT Clump#, PLT Clump%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%, PDW-SD, NLR, PLR, Neu-X, Neu-Y, Neu-Z, Lym-X, Lym-Y, Lym-Z, Mon-X, Mon-Y, Mon-Z

3 histograms for WBC, RBC and PLT

4 scattergrams for WBC differential

Reagent

M-52D Diluent, M-52DIFF Lyse, M-52LH Lyse, Probe Cleanser

Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10 ⁹ /L	≤2% (4-15×10 ⁹ /L)	≤0.5%
RBC	0-8×10 ¹² /L	≤1.5% (3.5-6.0×10 ¹² /L)	≤0.5%
HGB	0-250g/L	≤1.5% (110-180g/L)	≤0.6%
PLT	0-5000×10 ⁹ /L	≤6.0% (100-149×10 ⁹ /L) ≤4.0% (150-500×10 ⁹ /L)	≤1.0%

Sample Volume

Prediluted mode	20 µL
Whole blood mode	15 µL
Capillary whole blood mode	15 µL

Throughput

60 samples per hour

Display

10.4 inch TFT Touch Screen

Multi-language

Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity

Up to 250,000 results including numeric and graphical information

Communication

LAN port supports HL7 protocol

Interface

USB, LAN

Support bi-directional LIS

Printout

External Thermal printer / Laser printer / Inkjet printer, various printout formats and user-defined formats

Operating Environment

Temperature: 10°C~30°C

Humidity: 20%~85%

Air pressure: 70 kPa~106 kPa

Power requirement

100V-240V

50Hz/60Hz

Dimension and Weight

Depth(400 mm) x width(320 mm) x height(410 mm)

Weight :24kg



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 044751 0164 Rev. 07

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Service and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 07

Report No.: SH25005503

Valid from: 2025-07-07

Valid until: 2026-08-31

Date, 2025-07-09

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 044751 0164 Rev. 07

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis,
anesthesia, breathing and intensive care; In-vitro Diagnostic
Instruments; Non-active accessories for breathing therapy and
anesthesia; In-vitro diagnostic reagents and kits(intended) for
hematology, clinical chemistry, immunology and cell analysis.
Patient Monitor and Accessories, Vital Signs Monitor, Center
Monitoring System, Telemetry Monitoring System, Pulse Oximeter,
Temperature Probe, Flow Sensor, Ambulatory Blood pressure
Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph,
Anesthesia Machine and accessories, Ventilator, Air compressor,
Endoscope Camera System, Endoscope Light Source and
accessories, Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System, Hematology
Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate
Reader, Microplate Washer for invitro diagnostic use,
Chemiluminescence Immunoassay Analyzer, Flow Cytometer,
(Auto) Sample Processing System, Auto Slide Maker&Stainer,
Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents
for Hematology Analyzer, Reagents for Clinical Chemistry
Analyzer, Chemiluminescence Immunoassay Reagents,
Chemiluminescence Immunoassay Calibrators and Controls,
Reagents for Flow Cytometer, Reagents for Glycohemoglobin
Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer,
Coagulation Analyzer and Accessories, Coagulation Reagents,
Calibrators and Controls for Coagulation Analyzer, Automated
Digital Cell Morphology Analyzer, Ion-Selective Electrodes,
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit, Reusable
Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing
Bag, Tympanic Thermometer, Microbial Analysis System,
Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong,
Detector and Imaging System, Hemoglobin A1c Analytical Column,
Respiratory Humidifier



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 044751 0164 Rev. 07

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis. Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System, Hemoglobin A1c Analytical Column, Respiratory Humidifier

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

A. Sizy
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei,**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of twelve (12) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- comply with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- are classified as Other Devices (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2018

P-Vila

Pau Vila Cases, PhD
CEO
BioSystems S.A.



• Certified Management System
• EN ISO 9001
• EN ISO 13485

PRODUCT NAME	CODE
CLINICAL CHEMISTRY - BIOCHEMISTRY	
a-AMYLASE - DIRECT	11583
	11550
	12550
	21550
	23550
a-AMYLASE - EPS	11534
	21534
a-AMYLASE-PANCREATIC	11799
	12799
	21799
ACID PHOSPHATASE (ACP)	11548
ALANINE AMINOTRANSFERASE (ALT/GPT)	11832
	11533
	11568
	11562
	12533
	21533
	23533
ALBUMIN	11573
	11547
	12547
	21547
	23547
ALKALINE PHOSPHATASE (ALP) - AMP	11592
	11593
	11598
	12518
	21592
	23592
ALKALINE PHOSPHATASE (ALP) - DEA	11590
	11591
	11597
	12514
	21590
	23590
ASPARTATE AMINOTRANSFERASE (AST/GOT)	11830
	11531
	11567
	11561
	12531
	21531
	23531
BILIRUBIN (DIRECT)	11511
	11545
	21504

PRODUCT NAME	CODE
	23504
BILIRUBIN (TOTAL AND DIRECT)	11515
	11555
BILIRUBIN (TOTAL)	11510
	11544
	21506
	23506
CALCIUM-ARSENazo	11570
	11571
	12570
	21570
	23570
CALCIUM-CRESOLPHTHALEIN	11811
	11812
	12513
	21511
	23511
CALCIUM-MTB	11527
	11507
CARBON DIOXIDE (CO2)	11558
	11827
	12558
	21558
CHOLESTEROL	11805
	11505
	11506
	11539
	12505
	21505
	23505
CHOLESTEROL HDL	11523
CHOLESTEROL HDL DIRECT	11557
	12557
	21557
	23557
CHOLESTEROL HDL PRECIPITATING REAGENT	11648
CHOLESTEROL LDL DIRECT	11585
	12585
	21585
	23585
CHOLESTEROL LDL PRECIPITATING REAGENT	11579
CHOLINESTERASE (CHE)	11588
	11589
	21588
CITRATE	11795
	11895
	23795
CREATINE KINASE (CK)	11790
	11791
	12524
	21790

P.V.

PRODUCT NAME	CODE
	23790
CREATINE KINASE-MB (CK-MB)	11792
	12566
	21792
	23792
CREATININE	11802
	11502
	11542
	12502
	21502
	23502
CREATININE-ENZYMATIC	11734
	12734
	21734
FRUCTOSAMINE	11046
FRUCTOSE	11794
	23794
g-GLUTAMYLTRANSFERASE (g-GT)	11584
	11520
	12520
	21520
	23520
GLUCOSE	11803
	11503
	11504
	11538
	12503
	21503
	23503
GLUCOSE-HEXOKINASE	11656
	12756
	21656
	23656
IRON- CHROMAZUROL	11546
IRON-FERROZINE	11509
	12509
	21509
	23509
LACTATE	11736
	12736
	21736
	23736
LACTATE DEHYDROGENASE (LDH)	11580
	11581
	12580
	21580
	23580
LACTATE DEHYDROGENASE (LDH) - IFCC	11586
	11587
	21586
	23586

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PRODUCT NAME	CODE
LIPASE	11793
	12793
	23793
MAGNESIUM	11797
	12797
	21797
	23797
PHOSPHORUS	11508
	12508
	21518
	23518
PROTEIN (TOTAL)	11800
	11572
	11500
	11553
	12500
	21513
	23513
PROTEIN (URINE)	11501
	11559
	12501
	21512
	23512
PYRIDOXAL PHOSPHATE	11666
TOTAL IRON BINDING CAPACITY (TIBC)	11554
TRIGLYCERIDES	11828
	11528
	11529
	12528
	21528
	23528
UNSATURATED IRON BINDING CAPACITY (UIBC)	11835
	12835
	21835
UREA/BUN - COLOR	11536
	11537
UREA/BUN - UV	11516
	11517
	11541
	12516
	21516
	23516
URIC ACID	11821
	11521
	11522
	11540
	12521
	21521
	23521
ZINC	12526
CLINICAL CHEMISTRY - TURBIDIMETRY	

PRODUCT NAME	CODE
a1-ACID GLYCOPROTEIN	31928
	23107
ALBUMIN (MICROALBUMINURIA)	31324
	31924
	13324
	22324
	23324
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	61004
	61005
	61009
ANTI-STREPTOLYSIN O (ASO)	31323
	31923
	31031
	13923
	22923
	23923
ANTITHROMBIN III	31936
	13936
	22936
	23936
APOLIPOPROTEIN A-I (APO A-I)	31095
	23095
APOLIPOPROTEIN B (APO B)	31098
	23098
b2-MICROGLOBULIN	31925
	22925
	23925
COMPLEMENT COMPONENT C3	31073
	31079
	13084
	23103
COMPLEMENT COMPONENT C4	31074
	31080
	13085
	23104
C-REACTIVE PROTEIN (CRP)	31321
	31921
	31029
	13921
	22921
	23921
C-REACTIVE PROTEIN-hs (CRP-hs)	31927
	13927
	22927
	23927
FERRITIN	31934
	31935
	22934
	23934
	13934

2-4-1

PRODUCT NAME	CODE
FIBRINOGEN	31600
	13600
	22804
	23804
FIBRINOGEN CLAUSS	61002
	61003
	61020
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)	31047
	13047
	22047
	22147
IMMUNOGLOBULIN A (IgA)	31071
	31077
	13082
	23101
IMMUNOGLOBULIN G (IgG)	31070
	31076
	13081
	23100
IMMUNOGLOBULIN M (IgM)	31072
	31078
	13083
	23102
PREALBUMIN	31929
	23106
PROTHROMBIN TIME (PT)	61001
RHEUMATOID FACTORS (RF)	31322
	31922
	31030
	13922
	22922
	23922
THROMBIN TIME (TT)	61000
TRANSFERRIN	31091
	31092
	31093
	13091
	22105
	23105
CLINICAL CHEMISTRY - MICROCOLUMN CHROMATOGRAPHY	
17-HYDROXYCORTICOSTEROIDS (17-OH)	11006
17-KETOSTEROIDS	11002
5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)	11017
5-HYDROXYINDOLEACETIC ACID (5-HIAA)	11010
HEMOGLOBIN A2	11077
METANEPHRINES	11022
VANILMANDELIC ACID	11003
CLINICAL CHEMISTRY - STANDARDS & CALIBRATORS	

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PRODUCT NAME	CODE
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	18011
AMMONIA/ETHANOL/CO2 CALIBRATOR	18065
ANTI-STREPTOLYSIN O (ASO) STANDARD	31119
APOLIPOPROTEIN A-I (APO A-I) STANDARD	31100
APOLIPOPROTEIN B (APO B) STANDARD	31200
b2-MICROGLOBULIN STANDARD	31122
BILIRUBIN STANDARD	11693
BIOCHEMISTRY CALIBRATOR	31075
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
CARBON DIOXIDE STANDARD	11822
	11833
CHOLESTEROL HDL/LDL CALIBRATOR	11824
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11750
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11603
PREALBUMIN STANDARD	31196
PROTEIN (URINE) STANDARD	31130
PROTEIN CALIBRATORS	11513
RHEUMATOID FACTORS (RF) STANDARD	31116
CLINICAL CHEMISTRY - INSTRUMENTS	
A15	83105
A25	83101
BA400	83400
BA200	83200
BTS-350	80175
CONSUMABLES (INSTRUMENTS)	
ALKALINE WASHING SOLUTION	AC17204
	AC17205
ACID WASHING SOLUTION	AC17200
	AC17201
CONCENTRATED SYSTEM LIQUID	BO11524
CONCENTRATED SYSTEM LIQUID 2	AC17206
CONCENTRATED WASHING SOLUTION	BO13416
	AC16434
Reaction Rotor	AC11485
Sample Wells (1000 units)	AC10770
WASHING SOLUTION	AC10415
	BO10771
CLINICAL CHEMISTRY - BIOCHEMISTRY - REAGENTS AUTOMATED SYSTEMS A15/A25	
ADENOSINE DEAMINASE (ADA)	12754
	23754
AMMONIA	12532
	23532

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PRODUCT NAME	CODE
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796
	21796
b-HYDROXYBUTYRATE	12525
	21525
ETHANOL	12789
	21789
HOMOCYSTEINE	12737
	21737
	23737
OXALATE	12539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551
	21551
	23551
a-1-Microglobulin	22941
C-REACTIVE PROTEIN-er (CRP-er)	22942
	23942
CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL	
ADA CONTROLS	18048
AMMONIA/ETHANOL/CO2 CONTROL I	18063
AMMONIA/ETHANOL/CO2 CONTROL II	18064
b2-MICROGLOBULIN CONTROL URINE	31215
b2-MICROGLOBULIN CONTROLS	31592
BIOCHEMISTRY CONTROL SERUM (HUMAN) I	18042
BIOCHEMISTRY CONTROL SERUM (HUMAN) II	18043
BIOCHEMISTRY CONTROL SERUM I	18009
	18005
BIOCHEMISTRY CONTROL SERUM II	18010
	18007
BIOCHEMISTRY CONTROL URINE	18054
BIOCHEMISTRY CONTROL URINE II	18066
CK-MB CONTROL SERUM	18024
CK-MB CONTROL SERUM II	18061
COAGULATION CONTROL I	61007
COAGULATION CONTROL II	61008
CONTROL URINE	18036
	18037
FERTILITY BIOCHEMISTRY CONTROL	18053
FIBRINOGEN CONTROL PLASMA	31602
FRUCTOSAMINE CONTROL SERUM	18057
HEMOGLOBIN A1C CONTROL (ELEVATED)	18002
HEMOGLOBIN A1C CONTROL (NORMAL)	18001
HEMOGLOBIN A2 CONTROL	10011
HOMOCYSTEINE CONTROL I	18058
HOMOCYSTEINE CONTROL II	18059
LIPID CONTROL SERUM I	18040
LIPID CONTROL SERUM II	18041
OXALATE CONTROL URINE	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212

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PRODUCT NAME	CODE
RHEUMATOID CONTROL SERUM I	31213
RHEUMATOID CONTROL SERUM	31214
AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE)	
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	44574
	44575
	29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148
	44548
	44715
	44557
	44710
ANTI-ISLET CELL ANTIBODIES (AICA)	44609
	44572
ANTI-KERATIN ANTIBODIES (AKA)	44618
	44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510
	44514
	44511
	44515
ANTI-nDNA ANTIBODIES (nDNA)	44825
	44818
	44817
	44820
	44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850
	44851
	44852
	44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)	44108
	44508
	44509
	44546
	44547
ANTI-NUCLEAR ANTIBODIES RL (ANA-RL)	44506
	44507
ANTI-SKIN ANTIBODIES (ASA)	44560
	44561
ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)	44520
	44524
	44521
	44525
ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)	44649
	29017
ANTI-THYROID ANTIBODIES (ATA)	44550
	44551
	29012
AUTOANTIBODIES DUO-HEp2/ML (DUO-HEp2/ML)	44874
AUTOANTIBODIES MSK/MSS (AA-MSK/MSS)	44518
AUTOANTIBODIES MSL/MSK/MSS (AA-MSL/MSK/MSS)	44826
	44827

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PRODUCT NAME	CODE
AUTOANTIBODIES-RK/RS (AA-RK/RS)	44758
	44568
AUTOANTIBODIES-RL/RK/RS (AA-RL/RK/RS)	44558
	44648
	44570
	44639
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	44588
AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS	
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549
	44893
	44732
AICA POSITIVE CONTROL	44577
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
	44891
ANA-Ce POSITIVE CONTROL	44585
ANA-Ho POSITIVE CONTROL	44502
	44890
ANA-Nu POSITIVE CONTROL	44504
ANA-Sp POSITIVE CONTROL	44503
APCA POSITIVE CONTROL	44532
ASA-bm POSITIVE CONTROL	44562
ASA-is POSITIVE CONTROL	44563
ASMA POSITIVE CONTROL	44522
	44892
AStMA POSITIVE CONTROL	44883
ATA POSITIVE CONTROL	44553
BLOTTING PAPER 12	44669
BLOTTING PAPER 4	44731
BLOTTING PAPER 6	44667
BLOTTING PAPER 8	44716
C-ANCA POSITIVE CONTROL	44854
	44912
FITC/EVANS (R)	44590
	44836
	44916
GBMA POSITIVE CONTROL	44678
GLYCIN	44846
IgA FITC/EVANS	44692
	44835
IgG FITC/EVANS	44697
	44834
IgG FITC/EVANS (M)	44847
	44882
LKM POSITIVE CONTROL	44766
MOUNTING MEDIUM	44694
nDNA POSITIVE CONTROL	44542
	44894

24/11

PRODUCT NAME	CODE
NEGATIVE CONTROL	44696
	44889
P-ANCA POSITIVE CONTROL	44855
	44913
PBS (10x)	44592
X-ANCA POSITIVE CONTROL	44896
AUTOIMMUNITY - ELISA	
ANA-SCREENING	44785
ANTI-ANNEXIN V IgG/IgM (ANX)	44869
ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)	44868
ANTI-BPI ANTIBODIES	44905
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	44780
ANTI-CATHEPSIN G ANTIBODIES	44906
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	44865
ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	44860
ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)	44885
ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)	44884
ANTI-dsDNA ANTIBODIES	44705
ANTI-ELASTASE ANTIBODIES	44907
ANTI-GBM ANTIBODIES-EIA (GBM)	44870
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	44704
ANTI-HISTONES ANTIBODIES (HIS)	44862
ANTI-INSULIN ANTIBODIES (INS)	44873
ANTI-Jo1 ANTIBODIES	44864
ANTI-LACTOFERRIN ANTIBODIES	44908
ANTI-LYSOZYME ANTIBODIES	44909
ANTI-M2 ANTIBODIES (M2)	44871
ANTI-MPO ANTIBODIES (P-ANCA)	44790
ANTI-NUCLEOSOME ANTIBODIES (NCL)	44861
ANTI-PHOSPHOLIPID IgG/IgM (APLA)	44867
ANTI-PR3 ANTIBODIES (C-ANCA)	44791
ANTI-RIBOSOMAL P ANTIBODIES (Rib P)	44866
ANTI-Sci70 ANTIBODIES	44863
ANTI-Sm ANTIBODIES	44755
ANTI-Sm/RNP ANTIBODIES	44770
ANTI-SSA (Ro) ANTIBODIES	44765
ANTI-SS-B (La) ANTIBODIES	44750
ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)	44796
ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO)	44795
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)	44754
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)	44798
ASCA-IgG/IgA (ASCA)	44872
ENA 4-PROFILE	44775
ENA 6-PROFILE	44910
ENA 6-SCREENING	44740
AUTOIMMUNITY - INSTRUMENTS	

2-2-1

PRODUCT NAME	CODE
iPRO	84101
RAPID TESTS - LATEX AGGLUTINATION	
ANTI-STREPTOLYSIN O (ASO) - SLIDE	31019
	31319
	31086
	31448
C-REACTIVE PROTEIN (CRP) - SLIDE	31011
	31311
	31012
	31107
RHEUMATOID FACTORS (RF) - SLIDE	31013
	31313
	31014
	31108
INFECTIOUS IMMUNOLOGY - SYPHILIS	
RPR-CARBON	36001
	36002
TPHA	36005
INFECTIOUS IMMUNOLOGY - FEBRILE ANTIGENS	
BRUCELLA ABORTUS	33309
BRUCELLA ABORTUS, ROSE BENGAL	33315
BRUCELLA POSITIVE CONTROL	33509
FEBRILE SERODIAGNOSTICS MULTISCREENING	33001
FEBRILE SERODIAGNOSTICS SALMONELLA	33080
	33081
PROTEUS OX19	33311
PROTEUS POSITIVE CONTROL	33502
SALMONELLA PARATYPHI AH	33301
SALMONELLA PARATYPHI AO	33302
SALMONELLA PARATYPHI BH	33303
SALMONELLA PARATYPHI BO	33304
SALMONELLA PARATYPHI CH	33305
SALMONELLA PARATYPHI CO	33306
SALMONELLA POSITIVE CONTROL	33510

P-6.1.

Product-version: 0129-003

EU Declaration of Conformity

Name and address of the manufacturer: **BioSystems S.A. - Costa Brava, 30 08030 Barcelona (Spain)**
Name and address of the EC REP: **N/A**
Single Registration Number (SRN): **ES-MF-000000231**

We declare under our sole responsibility that:

The IVD medical device

BA200

together with the spare parts, accessories and consumables mentioned in the User and/or Service Manuals

with Intended use

Automatic analyser is used to determine analyte concentrations by in vitro biochemical, turbidimetric and electrolyte measurements of human samples of serum, urine, plasma, cerebrospinal fluid or total blood. The analyser is exclusively for professional use, i.e., for users who have the appropriate training and expertise to use it.

of Risk class

A

with Reference:	Brandname	with Basic UDI-DI:
83200	BioSystems	8435287191BA20000000GX
83200ISE	BioSystems	8435287191BA20000000GX
AC11485	BioSystems	84352871REACTIONROSW

Is in conformity with the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

And with the following relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Directive **2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.

Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Commission Delegated Directive **2015/863/EU** amending Annex II to Directive 2011/65/EU European Parliament and Council as regards the list of restricted substances.

Common specifications:

N/A

Name and identification no. of the NB:

The conformity assessment procedure for non-sterile class A devices should be carried out under the sole responsibility of the manufacturer, without Notified Body intervention.

Conformity assessment procedures:

ANNEX IX Full Quality System

Id. of the certificate:

N/A

Other information:

N/A

Place: Barcelona

Name and date:

On behalf of BioSystems S.A.

as Person Responsible for

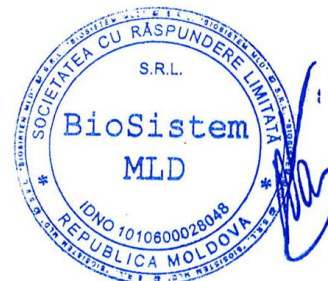
Regulatory Compliance (PRRC)



Teresa Cortes Colome

2022.05.25 15:57:35

+02'00'



Product-version: 0123-003

EU Declaration of Conformity

Name and address of the manufacturer: **BioSystems S.A.- Costa Brava, 30 08030 Barcelona (Spain)**
Name and address of the EC REP: **N/A**
Single Registration Number (SRN): **ES-MF-000000231**

We declare under our sole responsibility that:

The IVD medical device **A25**
together with the spare parts, accessories and consumables mentioned in the User and/or Service Manuals
with Intended use **Automatic analyser to determine analyte concentrations by in vitro biochemical and turbidimetric measurements of human samples of serum, urine, plasma, cerebrospinal fluid or total blood. The analyser is exclusively for professional use, i.e., for users who have the appropriate training and expertise to use it.**
of Risk class **A**

with Reference:	Brandname	with Basic UDI-DI:
83101	BioSystems	8435287191A2500000007R
AC11485	BioSystems	84352871REACTIONROSW

Is in conformity with the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

And with the following relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Directive **2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.

Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Commission Delegated Directive **2015/863/EU** amending Annex II to Directive 2011/65/EU European Parliament and Council as regards the list of restricted substances.

Common specifications:

Name and identification no. of the NB:

N/A

The conformity assessment procedure for non-sterile class A devices should be carried out under the sole responsibility of the manufacturer, without Notified Body intervention.

ANNEX IX Full Quality System

Conformity assessment procedures:

Id. of the certificate:

N/A

Other information:

N/A

Place: Barcelona

Name and date:

On behalf of BioSystems S.A.

as Person Responsible for

Regulatory Compliance (PRRC)

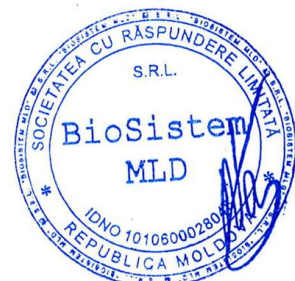


Teresa Cortes

Colome

2022.05.25

15:54:47 +02'00'



Product-version: 0124-003

EU Declaration of Conformity

Name and address of the manufacturer: **BioSystems S.A.- Costa Brava, 30 08030 Barcelona (Spain)**
Name and address of the EC REP: **N/A**
Single Registration Number (SRN): **ES-MF-000000231**

We declare under our sole responsibility that:

The IVD medical device

A15

together with the spare parts, accessories and consumables mentioned in the User and/or Service Manuals

with Intended use

Automatic analyser to determine analyte concentrations by in vitro biochemical and turbidimetric measurements of human samples of serum, urine, plasma, cerebrospinal fluid, total blood or stool . The analyser is exclusively for professional use, i.e., for users who have the appropriate training and expertise to use it.

of Risk class

A

with Reference:	Brandname	with Basic UDI-DI:
83105	BioSystems	8435287191A15000000072
83105C	BioSystems	8435287191A15000000072
83105S	BioSystems	8435287191A15000000072
AC11485	BioSystems	84352871REACTIONROSW

Is in conformity with the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

And with the following relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Directive **2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.

Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Commission Delegated Directive **2015/863/EU** amending Annex II to Directive 2011/65/EU European Parliament and Council as regards the list of restricted substances.

Common specifications:

N/A

Name and identification no. of the NB:

The conformity assessment procedure for non-sterile class A devices should be carried out under the sole responsibility of the manufacturer, without Notified Body intervention.

Conformity assessment procedures:

ANNEX IX Full Quality System

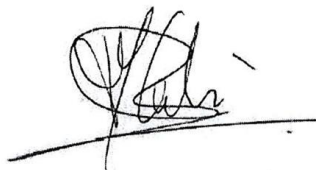
Id. of the certificate:

N/A

Other information:

N/A

Place: Barcelona
Name and date:
On behalf of BioSystems S.A.
as Person Responsible for
Regulatory Compliance (PRRC)



Teresa Cortes
Colome
2022.05.25 15:53:50
+02'00'



Product-version: 0122-003

EU Declaration of Conformity

Name and address of the manufacturer: **BioSystems S.A.- Costa Brava, 30 08030 Barcelona (Spain)**
Name and address of the EC REP: **N/A**
Single Registration Number (SRN): **ES-MF-000000231**

We declare under our sole responsibility that:

The IVD medical device

BA400

together with the spare parts, accessories and consumables mentioned in the User and/or Service Manuals

with Intended use

Automatic analyser to determine analyte concentrations by in vitro biochemical, turbidimetric and electrolyte measurements of human samples of serum, urine, plasma, cerebrospinal fluid or total blood. The analyser is exclusively for professional use, i.e., for users who have the appropriate training and expertise to use it.

of Risk class

A

with Reference:	Brandname	with Basic UDI-DI:
83400	BioSystems	8435287191BA4000000J5
83400ISE	BioSystems	8435287191BA4000000J5
AC11485	BioSystems	84352871REACTIONROSW

Is in conformity with the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

And with the following relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Directive **2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.

Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Commission Delegated Directive **2015/863/EU** amending Annex II to Directive 2011/65/EU European Parliament and Council as regards the list of restricted substances.

Common specifications:

N/A

Name and identification no. of the NB:

The conformity assessment procedure for non-sterile class A devices should be carried out under the sole responsibility of the manufacturer, without Notified Body intervention.

Conformity assessment procedures:

ANNEX IX Full Quality System

Id. of the certificate:

N/A

Other information:

N/A

Place: Barcelona

Name and date:

On behalf of BioSystems S.A.

as Person Responsible for

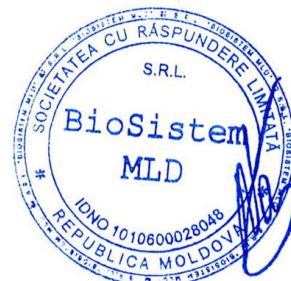
Regulatory Compliance (PRRC)



Teresa Cortes Colome

2022.05.25 16:00:34

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Product-version: 0504-001

EU Declaration of Conformity

Name and address of the manufacturer: **BioSystems S.A.- Costa Brava, 30 08030 Barcelona (Spain)**
Name and address of the EC REP: **N/A**
Single Registration Number (SRN): **ES-MF-000000231**

We declare under our sole responsibility that:

The IVD medical device **BTS**
together with the spare parts, accessories and consumables mentioned in the User and/or Service Manuals
with Intended use **Semi-automatic analyzer to determine analyte concentrations using in vitro biochemistry, and turbidimetry measurements on human samples of serum, urine, plasma, cerebrospinal fluid, seminal plasma or whole blood. The semi-automatic analyzer is for professional use only, for users with adequate training and capacity for its use.**

of Risk class **A**

with Reference:	Brandname	with Basic UDI-DI:
83000	BioSystems	8435287191BTS0000000HP

Is in conformity with the requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices

And with the following relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Directive **2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on machinery.

Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Commission Delegated Directive **2015/863/EU** amending Annex II to Directive 2011/65/EU European Parliament and Council as regards the list of restricted substances.

Common specifications:

Name and identification no. of the NB:

N/A

The conformity assessment procedure for non-sterile class A devices should be carried out under the sole responsibility of the manufacturer, without Notified Body intervention.

Conformity assessment procedures:

Id. of the certificate:

ANNEX IX Full Quality System

Other information:

N/A

N/A

Place: Barcelona
Name and date:
On behalf of BioSystems S.A.
as Person Responsible for
Regulatory Compliance (PRRC)



Teresa Cortes Colome
2022.05.25 16:11:20
+02'00'



Shenzhen Mindray Bio-Medical Electronics
Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China
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Fax: +86 755 26582500

DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

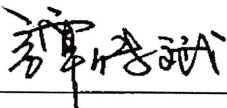
We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

Product Category(ies): Clinical Chemistry and Hematology Analyzers, Eliza washer, Eliza reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer Analyzer, Reagents for Clinical Chemistry, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis reagent strips.

Products: Attachment I

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, 2016-03-21



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

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ATTACHMENT I

Product Name	Product Model	Accessories
Auto Hematology Analyzer	BC-2300 BC-2100	M-23CFL LYSE M-23D DILUENT M-23E E-Z CLEANSER M-23P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-1800 BC-1900 BC-2900	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator BC-3D Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-3000 Plus	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3200 BC-3200CT	M-30D DILUENT M-30R RINSE

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		M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500 BC-5200	M-50D DILUENT M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300 BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator

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Auto Hematology Analyzer	BC-5380 BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800 BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300 BC-3300CT BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology

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		Calibrator
Auto Hematology Analyzer	BC-6600 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150 BC-5000	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator

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Urine Analyzer	UA-66、UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、BC-21s、 BC-30s、BC-31s	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent	/	/
CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent	/	/
HLA-B27 Reagent	/	/
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode

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		Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420、 BS-480、BS-490	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit

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		Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent

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		bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、 BS-180、BS-190	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-230、BS-240	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode

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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-430、BS-450	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml

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		Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、 BS-800M 、 BS-820M 、 BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)
Chemistry Analyzer	BS-2000 、 BS-2000M 、 BS-2200 、 BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance

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Chemistry Analyzer	BS-600、BS-620	System (RMS) ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemiluminescence Immunoassay Analyzer	CL-2000i CL-2200i	Hand-held bar code reader External vacuum pump External air pump Water supply module
Chemiluminescence Immunoassay Analyzer	CL-1000i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. Waste container
Chemiluminescence Immunoassay Analyzer	CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Hand-held bar code reader Reaction cuvettes. Waste container
α -Amylase (α -AMY) Kit (IFCC Method)	/	/
Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/

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Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.)	/	/
Lactate Dehydrogenase (LDH) Kit (IFCC Method)	/	/
Alanine Aminotransferase (ALT) Kit (IFCC Method)	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromcresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
α -Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/

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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turbidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/

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Creatine Kinase-MB Kit(IFCC Method)	/	/
HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N	/	/
Multi Control Sera P		
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N	/	/
Lipids Control P		
CK-MB Control N	/	/
CK-MB Control P		
Specific Proteins Control N	/	/
Specific Proteins Control P		
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/

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Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbumin (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimune Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α -L-Fucosidase Kit (CNPF method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/

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Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/
CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
aso Calibrator	/	/
Free Triiodothyronine (CLIA)	/	/
Free Thyroxine (CLIA)	/	/
Total Triiodothyronine (CLIA)	/	/
Total Thyroxine (CLIA)	/	/
Thyroid-stimulating Hormone (CLIA)	/	/
Follicle Stimulating Hormone (CLIA)	/	/
Luteinizing Hormone (CLIA)	/	/
Prolactin (CLIA)	/	/
Estradiol (CLIA)	/	/
Estriol (CLIA)	/	/
Testosterone (CLIA)	/	/
Progesterone (CLIA)	/	/
Total β Human Chorionic Gonadotropin (CLIA)	/	/

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Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total HCG Calibrators	/	/
Thyroid Function Multi Control	/	/
Reproductive Hormone Multi Control	/	/
Carcinoembryonic Antigen (CLIA)	/	/
Alpha-fetoprotein (CLIA)	/	/
Cancer Antigen 125 (CLIA)	/	/
Cancer Antigen 15-3 (CLIA)	/	/
Carbohydrate Antigen 19-9 (CLIA)	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" Kit (ASO II) (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF Triple Control	/	/
Cystatin C Kit (CysC II) (Latex Immunoturbidimetric Method)	/	/

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Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein Kit (Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor Kit (RF II) (Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
β 2-Microglobulin Kit (β 2-MG II) (Latex Immunoturbidimetric Method)	/	/
β 2-Microglobulin Control	/	/
β 2-Microglobulin Calibrator (for Serum)	/	/
β 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/
Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β -Hydroxybutyrate (β -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)		
HbA1c control N		
HbA1c control P		
Rheumatism Control N		
Rheumatism Control P		
HCY Control N		
HCY Control P		
FUN Control P		
β 2-MG Control		
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/

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MYO Calibrator	/	/
IgE Calibrator	/	/
β -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I(CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide(CLIA)	/	/
BNP Calibrators	/	/
Myoglobin(CLIA)	/	/
MYO Calibrators	/	/
Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotrophic hormone(CLIA)	/	/
ACTH Calibrators	/	/

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Cardiac Marker Multi Control	/	/
Thyroid Function Multi Control	/	/
Immunoassay Multi Control	/	/
ACTH Control	/	/
Anti-thyroid Antibodies Control	/	/
System Detection Solution	/	/
System Wash Solution	/	/
ClinChem Multi Control	/	/
Sample Diluent		

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1695779-1
Certificate Holder: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope: The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.
The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92837241-30
Effective date: 2025-12-13
Expiry date: 2028-12-12
Issue date: 2025-11-14
Replaces certificate SX 1695779-1 issued 2022-12-12

This certificate can be validated on <https://www.certipedia.com>


Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1695779-1
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Costa Brava 30
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Spain

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry. The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapióles Naves 12, 13, 21, 22 08010 Montcada i Reixac - Barcelona	Labelling, assembling, warehousing and shipment of in vitro diagnostic tests kits for clinical chemistry and immunochemistry. Warehousing and shipment of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.

This certificate can be validated on <https://www.certipedia.com>