



# BC "MOLDINDCONBANK" S.A. Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chişinău, 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  
in moneda nationala 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

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*

*L. Svirepova*  
semnătura

MD 0101250





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.  
Secția fonduri speciale și informații curente

**EXTRAS**  
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 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,**

Asociați:

- 1. POIATA VITALIE , IDNP 0983103892591**  
cota 1803.60 lei, ce constituie 33,4 %
- 2. NASEDCHIN ALEXANDR , IDNP 2002001070747**  
cota 1798.20 lei, ce constituie 33,3 %
- 3. KOJEVNIKOV DMITRII , IDNP 0972305012362**  
cota 1798.20 lei, ce constituie 33,3 %.

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: 11.07.2016.

Specialist principal  
tel. 022-266-252

  
**Lazari Aliona**



## **Lista fondatorilor Biosistem-mld SRL**

<b>Nr.</b>	<b>Nume, Prenume</b>	<b>IDNP</b>
<b>1.</b>	<b>Vitalie Poiata</b>	<b>0983103892591</b>
<b>2.</b>	<b>Alexandru Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2026688**

din  
от **28.10.2020**

**1. Destinația / Назначение**

Pentru participarea la proceduri de achiziții publice

**2. Date despre contribuabil / Информация о налогоплательщике**

<b>Denumirea</b> Наименование	<b>Codul fiscal / Numărul de identificare</b> Фискальный код / Идентификационный номер
<b>BIOSISTEM MLD S.R.L.</b>	<b>1010600028048</b>
<b>Adresa sediului de bază (strada, numărul)</b> Адрес основного месторасположения (улица, номер)	<b>Codul - Denumirea localității</b> Код - Наименование населенного пункта
<b>Albisoara nr.16 bl.1 of.7</b>	<b>0150-SEC.RISCANI</b>

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /**

Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:  
**0,00 lei/лей.**

**4. Valabil până la / Действителен до 12.11.2020**

**5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы**

**Şef DDF Rîșcani**  
**a DGAF mun.Chișinău**

Funcția/Dолжность

Семнатура/Подпись

**Viorica CĂUȘ**

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

**Claudia GOJAN**

Executor:

Numele și prenumele/Фамилия и имя



Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 28.10.2020 ora 15:29:00  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,62)



1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	050					
1	2	3	4	5	6	7
<b>Datorii pe termen lung - total</b>	060					
Datorii comerciale, inclusiv pe tari:	070					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050  
Rd.060= rd.070 + rd.080 + rd.090 + rd.100  
Col.7 = col.3+col.4+col.5+col.6

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

Tabelul 2

**Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor**

Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar		
1	2	3	4	5	6	7	
<b>Creante si investitii financiare pe termen lung - total</b>	010						
Creante comerciale, inclusiv pe tari:	020						
1	2	3	4	5	6	7	
Avansuri acordate, inclusiv pe tari:	030						
1	2	3	4	5	6	7	
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040						
1	2	3	4	5	6	7	
Depozite, inclusiv pe tari:	050						
1	2	3	4	5	6	7	
Alte creante si investitii financiare, inclusiv pe tari:	060						
1	2	3	4	5	6	7	
<b>Datorii pe termen lung - total</b>	070						
Datorii comerciale, inclusiv pe tari:	080						
1	2	3	4	5	6	7	
Avansuri primite, inclusiv pe tari:	090						
1	2	3	4	5	6	7	

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60  
Rd.070= rd.080 + rd.090 + rd.100 + rd.110  
Col.7 = col.3+col.4+col.5+col.6

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

Tabelul 3

**Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti**

Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune
			Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7	
<b>Creante si investitii financiare curente - total</b>	010						
Creante comerciale, inclusiv pe tari:	020						
1	2	3	4	5	6	7	
Avansuri acordate, inclusiv pe tari:	030						
1	2	3	4	5	6	7	
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040						
1	2	3	4	5	6	7	
Alte creante si investitii financiare, inclusiv pe tari:	050						
1	2	3	4	5	6	7	
<b>Datorii curente - total</b>	060						
Datorii comerciale, inclusiv pe tari:	070						
1	2	3	4	5	6	7	
Avansuri primite, inclusiv pe tari:	080						
1	2	3	4	5	6	7	
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090						
1	2	3	4	5	6	7	
Datorii privind dividendele calculate, inclusiv pe tari:	100						
1	2	3	4	5	6	7	
Alte datorii, inclusiv pe tari:	110						

Rd.010= rd.020 + rd.030 + rd.040 + rd.050  
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110  
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

**Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor**

Tabelul 4

Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune		
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
<b>Creante si investitii financiare curente - total</b>	010								
Creante comerciale, inclusiv pe tari:	020								
1	2	3	4	5	6	7	8	9	10
Avansuri acordate, inclusiv pe tari:	030								
1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040								
1	2	3	4	5	6	7	8	9	10
Depozite, inclusiv pe tari:	050								
1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, inclusiv pe tari:	060								
1	2	3	4	5	6	7	8	9	10
<b>Datorii curente - total</b>	070								
Datorii comerciale, inclusiv pe tari:	080								
1	2	3	4	5	6	7	8	9	10
Avansuri primite, inclusiv pe tari:	090								
1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100								
1	2	3	4	5	6	7	8	9	10
Alte datorii, inclusiv pe tari:	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060  
Rd.070= rd.080 + rd.090 + rd.100 + rd.110  
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

Tabelul 5

**Investitii financiare in strainatate si participarea nerezidentilor in capitalul social**

Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/majorari	Iesiri/diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
<b>Investitii financiare</b>	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, inclusiv pe tari:	020				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, inclusiv pe tari:	030				
1	2	3	4	5	6

1	2	3	4	5	6
<b>Capital social</b>	040				
Cote de participatie si actiuni de pina la 10% inclusiv, inclusiv pe tari:	050				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, inclusiv pe tari:	060				

Rd.010= rd.020 + rd.030  
Rd.040= rd.050 + rd.060  
Col.6 = col.3+col.4+col.5

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

Tabelul 6

**Venituri si cheltuieli aferente tranzactiilor cu nerezidentii**

Indicatori	Cod rd./cod tara	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
<b>Venituri - total</b>	010		
Venituri aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	020		
1	2	3	4
Venituri din dobinzi aferente activitatii operationale si altor activitati, inclusiv pe tari:	030		
1	2	3	4
Venituri din dividende si participati in alte entitati, inclusiv pe tari:	040		
1	2	3	4
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, inclusiv pe tari:	050		
1	2	3	4
Alte venituri, inclusiv pe tari:	060		
1	2	3	4
<b>Cheltuieli - total</b>	070		
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	080		
1	2	3	4
Cheltuieli privind dobinzile, inclusiv pe tari:	090		
1	2	3	4
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, inclusiv pe tari:	100		
1	2	3	4
Alte cheltuieli, inclusiv pe tari:	110		

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060  
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

**NOTA INFORMATIVA privind relatiile cu nerezidentii**

Anexa 9

Tabelul 7

**Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere**

Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/majorari	Iesiri/diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, inclusiv pe tari:	010				
1	2	3	4	5	6

1	2	3	4	5	6
Bunuri primite spre prelucrare, inclusiv pe țări:	020				

1	2	3	4	5	6
Bunuri obținute din materialele prelucrate, inclusiv pe țări:	030				

Col.6 = col.3+col.4-col.5

### Informațiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
A	1	2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200								
2.1 brevete și mărci	210								
2.2 licențe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	500								
5.1. clădiri	510								
5.2. construcții speciale	520								
5.3. mașini, utilaje, instalații de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente și inventar	550								
5.6. costuri ulterioare aferente obiectelor neluate în bilanș	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590								
6. Resurse minerale	600								
7. Investiții imobiliare, total	700								

**Persoanele responsabile de semnarea rapoartelor financiare ale entității\***  
\* conform art. 36 din Legea contabilității

### Documente atașate - Notă explicativă (fișierul pdf)

Biosistem 2019.pdf

6/12/2020

View BNS receipt | Declarația electronică

Versiune de imprimare

Salva

## Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM.MLD.S.R.L.

A prezentat raportul: RSF1

Pentru perioada fiscală: A/2019

Data prezentării: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.05.2020 10:13:29

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

<https://declaratie-electronica.fisc.md/ro/declaration/11542429/receipt-bns?print=1>

1/1

6/12/2020

Afișează recipisa | Declarația electronică

Versiune de imprimare

Salva

## Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM.MLD.S.R.L.

A prezentat raportul: RSF1

Pentru perioada fiscală: A/2019

Data prezentării: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 31.03.2020 17:42:37

<https://declaratie-electronica.fisc.md/ro/declaration/11542429/receipt?print=1>

1/1





# **BIOSISTEM-MLD S.R.L.**

c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău  
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.  
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

**Către Grupul de lucru pentru evaluarea**

**Procedurii de achiziție ocds-b3wdp1-MD-1602657962830**

**din 05.11.2020**

**din cadrul IMSP AMT Buiucani**

## **Declarație**

Prin prezenta, SRL „Biosistem-mld”, declara ca

- Include suportul stiintific
- Dispune de persoane disponibile, instruite si autorizate de producatorul utilajului pentru a oferi servicii de suport tehnic, mentenanta, reparatie in caz de necesitate
- In caz de necesitate, va prezenta mostre timp de 1 zi de la instiintare
- Bunurile oferite in cadrul ofertei pentru aceasta procedura de achizitie publica sunt inregistrate in registrul de stat al dispozitivelor medicale sau urmeaza a fi inregistrate pana la momentul livrarii. Acest fapt poate fi verificat pe platforma Agenției Medicamentului și Dispozitivelor Medicale.

\_\_\_\_\_ Vitalie Poiata

**L.Ș.**

## ***CERTIFICAT DE AUTORIZARE***

Prin prezentul este autorizata

SRL Biosistem-MLD  
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica  
Moldova produsele

BIOSYSTEMS SA  
cu sediul C/Costa Brava 30  
08030 Barcelona (Spain)



Xavier Palomar  
Area Manager  
27-April-2013



## 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 five (5) 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:

- complies 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
- is classified as Other Device (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 6<sup>th</sup>, 2012


Dr. Antonio Elduque  
Managing director  
BioSystems S.A.



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



## **CLINICAL CHEMISTRY – BIOCHEMISTRY:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-EPS	Creatine Kinase-MB (CK-MB)
a-Amylase-Pancreatic	Creatinine
Acid Phosphatase (ACP)	Fructosamine
Alanine Aminotransferase (ALT/GPT)	Fructose
Albumin	g-Glutamyltransferase (g-GT)
Alkaline Phosphatase (ALP)-AMP	Glucose
Alkaline Phosphatase (ALP)-DEA	Iron – Chromazurol
AspartateAminotranferase (AST/GOT)	Iron – Ferrozine
Bilirubin (direct)	Iron Binding Capacity
Bilirubin (total and direct)	Lactate Dehydrogenase (LDH)
Bilirubin (total)	Lactate Dehydrogenase (LDH) – IFCC
Calcium – Arsenazo	Lipase
Calcium – MTB	Magnesium
Cholesterol	Phosphorus
Cholesterol HDL	Protein (total)
Cholesterol HDL direct	Protein (urine)
Cholesterol HDL Precipitating reagent	Pyridoxal Phosphate
Cholesterol LDL direct	Triglycerides
Cholesterol LDL Precipitating reagent	Urea/BUN-Color
Cholinesterase (CHE)	Urea/BUN-UV
Citrate	Uric Acid

## **CLINICAL CHEMISTRY – TURBIDIMETRY:**

a1-acid Glycoprotein	C-Reactive Protein (CRP)
Albumin (Microalbuminuria)	C-Reactive Protein-hs (CRP-hs)
Anti-Streptolysin O (ASO)	Ferritin
Antithrombin III	Immunoglobulin A (IgA)
Apolipoprotein A-I (Apo A-I)	Immunoglobulin G (IgG)
Apolipoprotein B (Apo B)	Immunoglobulin M (IgM)
b2-Microglobulin	Prealbumin
Complement Component C3	Rheumatoid Factors (RF)
Complement Component C4	Transferrin

## **CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:**

17-Hydroxycorticosteroids	Hemoglobin A1C
17-Ketosteroids	Hemoglobin A2
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)	Metanephrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid



## **CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:**

a-1-acid Glycoprotein Standard	Biochemistry Calibrator (Human)
Adenosine Deaminase (ADA) Standard	Cholesterol HDL/LDL Calibrator
Albumin (Microalbuminuria) Standard	CRP/CRP-hs Standard
Anti-Streptolysin O (ASO) Standard	Ferritin Standard
Antithrombin III Standard	Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Apolipoprotein A-I Standard	Prealbumin Standard
Apolipoprotein B Standard	Protein Calibrators
b2-Microglobulin Standard	Protein (urine) Standard
Bilirubin Standard	Rheumatoid Factors (RF) Standard
Biochemistry Calibrator	

## **CLINICAL CHEMISTRY – INSTRUMENTS:**

A15	BA400
A25	BTS-350

## **CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-Pancreatic	Creatine Kinase-MB (CK-MB)
Adenosine Deaminase (ADA)	Creatinine
Alanine Aminotransferase (ALT/GPT)	g-Glutamyltransferase (g-GT)
Albumin	Glucose
Alkaline Phosphatase (ALP)-AMP	Iron Ferrozine
Alkaline Phosphatase (ALP)-DEA	Lactate dehydrogenase (LDH)
Aspartate Aminotransferase (AST/GOT)	Lipase
Bilirubin (direct)	Magnesium
Bilirubin (total)	Phosphorus
Calcium-Arsenazo	Protein (total)
Cholesterol	Protein (urine)
Cholesterol HDL direct	Triglycerides
Cholesterol LDL direct	Urea/BUN UV
	Uric acid



## **CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:**

Albumin (Microalbuminuria)	Ferritin
Anti-Streptolysin O (ASO)	Hemoglobin A1C-Turbi (HbA1C-Turbi)
Antithrombin III	Immunoglobulin A (IgA)
Complement Component C3	Immunoglobulin G (IgG)
Complement Component C4	Immunoglobulin M (IgM)
C-Reactive Protein (CRP)	Rheumatoid Factors (RF)
C-Reactive Protein-hs (CRP-hs)	Transferrin

## **CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:**

ADA Controls	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) I	Hemoglobin A2 Control
Biochemistry Control Serum (Human) II	Lipid Control Serum I
Biochemistry Control Serum I	Lipid Control Serum II
Biochemistry Control Serum II	Protein Control Serum I
CK-MB Control Serum	Protein Control Serum II
Control Urine	Rheumatoid Control Serum I
Fertility Biochemistry Control	Rheumatoid Control Serum II
Hemoglobin A1C Control (Elevated)	

## **AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):**

Anti-Adrenal Cortex Antibodies (AACA)	Anti-Thyroid Antibodies (ATA)
Anti-Endomysium Antibodies (AEA)	Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Anti-Islet Cell Antibodies (AICA)	Autoantibodies MsK/MsS (AA-MsK/MsS)
Anti-Keratin Antibodies (AKA)	Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Anti-Mitochondrial Antibodies (AMA)	Autoantibodies RK/RS (AA-RK/RS)
Anti-nDNA antibodies (nDNA)	Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)	Glomerular Basement Membrane Antibodies (GBMA)
Anti-Nuclear Antibodies RL (ANA-RL)	
Anti-Skin Antibodies (ASA)	
Anti-Smooth Muscle Antibodies (ASMA)	
Anti-Striated Muscle Antibodies (AStMA)	



## ***AUTOIMMUNITY – ELISA:***

ANA Screening  
Anti-Annexin V IgG/IgM (ANX)  
Anti-b2-Glycoprotein 1 IgG/IgM  
(b2GP1)  
Anti-Cardiolipin Antibodies (ACA-  
IgG/IgM)  
Anti-Centromere B Antibodies (CENP-  
B)  
Anti-Citrullinated Protein Antibodies  
(ACPA)  
Anti-Deamidated Gliadin Peptides IgA  
(DGP IgA)  
Anti-Deamidated Gliadin Peptides IgG  
(DGP IgG)  
Anti-dsDNA Antibodies  
Anti-GBM Antibodies - EIA (GBM)  
Anti-Gliadin Antibodies (AGA-IgG/IgA)  
Anti-Histones Antibodies (HIST)  
Anti-Insulin Antibodies (INS)  
Anti-Jo1 Antibodies  
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies  
Anti-Nucleosome Antibodies (NCL)  
Anti-Phospholipid IgG/IgM (APLA)  
Anti-PR3 Antibodies  
Anti-Ribosomal P Antibodies (Rib P)  
Anti-Scl70 Antibodies  
Anti-Sm Antibodies  
Anti-Sm/RNP Antibodies  
Anti-SSA (Ro) Antibodies  
Anti-SSB (La) Antibodies  
Anti-Thyroglobulin Antibodies (Anti-Tg)  
Anti-Thyroid Peroxidase Antibodies  
(Anti-TPO)  
Anti-tTransglutaminase IgA Antibodies  
(Anti- tTG IgA)  
Anti-tTransglutaminase IgG Antibodies  
(Anti- tTG IgG)  
ASCA-IgG/IgA (ASCA)  
ENA 4-Profile  
ENA 6-Screening

## ***AUTOINMUNIDAD – INSTRUMENTOS:***

## ***AUTOIMMUNITY – INSTRUMENTS:***

iPRO



### ***RAPID TESTS – LATEX AGGLUTINATION:***

Anti-Streptolysin O (ASO) - Slide  
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

### ***INFECTIOUS IMMUNOLOGY – SYPHILIS:***

RPR-Carbon

TPHA

### ***INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:***

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**  
Costa Brava 30  
08030 Barcelona  
Spain

Scope: Design, development, manufacture, distribution, servicing of:  
-Instruments and reagents for clinical diagnostic.  
-Instruments and reagents for agro-alimentary analysis.  
Distribution and service of reagents and instruments for veterinary diagnosis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2019-12-19 until 2022-12-18.  
First certification 1996

2019-12-20



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

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Precisely Right.

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/02	BIOSYSTEMS S.A. Pol. Ind. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labeling and assembly of reagent. Storage, and shipping of: - Instruments and reagents for diagnosis and reagents for clinical diagnosis.- Instruments and reagents for agri-food analysis.- Instruments and reagents for veterinary diagnosis.

2019-12-20



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

Page 1 of 1

Klicken Sie hier, um Text einzugeben.

[www.tuv.com](http://www.tuv.com)

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# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**BIOSYSTEMS S.A.**  
**Costa Brava 30**  
**08030 Barcelona**  
**Spain**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and development, manufacture, distribution and  
servicing of instruments and reagents for  
clinical diagnostic  
(see attachment for sites included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-08  
Certificate Registration No.: SX 60145545 0001  
An audit was performed. Report No.: 28300434 004  
This Certificate is valid until: 2022-12-12

Certification Body



Date 2020-01-08



D. Swiatko

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60145545 0001  
**Report No.:** 28300434 004

**Organization:** BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

**Scope:**

Site included:

Polígono Industrial Can Tapioles  
Naves 7, 12 y 13  
08110 Montcada i Reixac  
Spain

Activity: Labelling and assembling of reagents,  
warehousing and shipment of instruments  
and reagents for clinical diagnostic

**Certification Body**



**Date: 2020-01-08**

**D. Swiatko**

Biosistem-mld SRL  
Albisoara 16/1 ap.7  
Chisinau, R.Moldova

16.10.2020

## MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("**Mindray**") manufacturer of Coagulation analyzer **C-3100**, hereby authorize: **Biosistem-mld SRL** with business office at Albisoara 16/1 ap.7 , Chişinău, R.Moldova, to as the **exclusive one company** to submit a bid, and subsequently negotiate and sign the Contract against for procurement of reagents, consumables and spare parts for the Coagulation analyzer C-3100 for the Tender organized by IMSP AMT Buiucani for the year 2021.

This authorization is valid from the date of issuance up to conclusion of the tender project. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any further compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Very truly yours,



Haijiao LUAN  
Deputy Manager of International Sales and Marketing System,  
Commonwealth of Independent States  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

# Declaration of Conformity



**Manufacturer:** Beijing Precil Instrument Co., Ltd.  
2F East 5 Building, Qunying kejyuan, Shangdi  
Information Base, Haidian District, Beijing 100085,  
China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

**Product:** Auto Coagulation Analyzer  
**Model:** C3100

**Consumables :** Auto Cuvettes  
Probe Cleanser  
Cleanser

**Classification:** Others(Not listed in the Annex II, Directive 98/79/EC)

**Conformity assessment route:** Annex III(Except 6), Directive 98/79/EC

**We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.**

**Standard applied:**

List of(harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2016-09-01

**Place, Date:** Beijing, 2016-09-01

**Signature:**

**Name of Authorized Signatory:** Zhang Yaohui

**Position Held in Company:** Management Representative

# Applied Standards List

**Product:** Auto Coagulation Analyzer

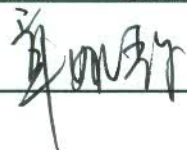
## Applied Standards:

EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN13640:2002	Stability testing of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-1)
EN ISO 15193:2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin
EN ISO 15194:2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
EN ISO 17511:2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 2: In vitro diagnostic reagents for professional use CORR: January 31, 2012
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements IEC 61326-1:2005
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements IEC 61010-1:2001
EN 61010-2-081:2002+A1:2003	Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2001
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)

**Drafted by:**



**Checked by:**





America

# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Certificate Holder:** 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:** See Page 2 for Overall Scope Statement.

**Standard(s):** ISO 13485:2016

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:** 65-467-1304

**Effective Date:** 2019-08-26

**Expiry Date:** 2021-10-23

Page 1 of 4

**Date of Issue:** 2019-11-25

( Dawn M. Tibodeau )  
 Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)





# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Regulatory Requirements:    Audit/Certification Criteria**

**Australia**

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

**Brazil**

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

**Canada**

- Medical Device Regulations SOR/98-282, Part 1

**United States**

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

**Overall Scope Statement:**

**Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

Page 2 of 4

Date of Issue: 2019-11-25



( Dawn M. Tibodeau )  
Manager, Certification Body MHS

# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**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

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

**Facility Scopes:**

**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 and Distribution of  
Medical Electronic Equipment (including Patient Monitor and  
Accessories (NIBP House, NIBP Cuff, Sensor Cables including  
SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG  
Cables and Leadsets, Temperature Probe, Probe Cover),  
Vital Signs Monitor, Center Monitoring System, Telemetry  
Monitoring System, Pulse Oximeter, Defibrillator / Monitor  
and Accessories, Electrocardiograph, Anesthesia Machine  
and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic  
Equipment, Ultrasonic Transducer, Hematology Analyzer,  
Clinical Chemistry Analyzer, Microplate Reader, Microplate  
Washer for In-Vitro Diagnostic Use, Chemiluminescence  
Immunossay Analyzer, Flow Cytometer, Auto Sample  
Processing System, Auto Slide Maker and Stainer;) Reagents  
for Hematology Analyzer, Reagents for Clinical Chemistry  
Analyzer, Chemiluminescence Immunoassay Reagents,  
Chemiluminescence Immunoassav Calibrators and Controls;  
Disposable Anesthesia Mask, Reusable Anesthesia Mask,  
Respiratory Mask, Disposable Breathing Circuit, Reusable  
Breathing Circuit, Heat and Moisture Exchanger, Filter,  
Breathing Bag  
DUNS No: 65-467-1304



( Dawn M. Tibodeau )  
Manager, Certification Body MHS



America

# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
 1203 Nanhuan Avenue, Guangming District, 518106, Shenzhen  
 PEOPLE'S REPUBLIC OF CHINA

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag  
 DUNS No: 54-459-5743

Page 4 of 4

Date of Issue: 2019-11-25

( Dawn M. Tibodeau )  
 Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT  
 TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Certificate Holder:** 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:** See Page 2 for Overall Scope Statement.

**Standard(s):** ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** SH2005501

**Effective Date:** 2020-08-12

**Expiry Date:** 2023-06-30

Page 1 of 4

**Date of Issue:** 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Overall Scope Statement**

**Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

Page 2 of 4

Date of Issue: 2020-08-20

Tina Israel  
 Manager, US Certification Body,  
 Medical and Health Services



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**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

**Facility Scopes:** Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 3 of 4

Date of Issue: 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Facility(ies)**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
 1203 Nanhuan Avenue, Guangming District, 518106  
 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**Facility Scopes:**

Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 4 of 4

Date of Issue: 2020-08-20

Tina Israel  
 Manager, US Certification Body,  
 Medical and Health Services

## CERTIFICATE

This is to certify that

Poiata Vitalie

Biosistem-mld SRL , Moldova

**For Successfully Completed the course**

Coagulation

C-3100

**Technical Training**

2018/07/28-2018/07/29

Q.H.Li  
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date:2018.07.29



## CERTIFICATE

This is to certify that

Nasedchin Alexandr

Biosistem-mld SRL , Moldova

**For Successfully Completed the course**

Coagulation

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