

-----:
ORDIN DE PLATA NR.: 36 TIP.DOC. 1 :
DATA EMITERII:mar?i, 28 ianuarie:
=====:
PLATITI: 6300-00 LEI: Sase Mii Trei Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) 'BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" SRL MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) I.M.S.P.Spi CONTUL DE PLATI/CODUL IBAN :
talul Raional Leova MD95TRPCCP518430C00072AA :
CODUL FISCAL :1003605150283 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat :TREZMD2X :
=====:
DESTINATIA PLATII:/P102/6300,00 Pentru g: TIPUL TRANSFERULUI :
arantia pentru oferta la procedura de ac: NORMAL/URGENT :N:
hizi?ie publica nr. ocds-b3wdpl-MD-17370: :
16985221 din 29.01.2025 : :
: :
: L.S. :
=====:
CODUL TRANZACTIEI:101: :
DATA PRIMIRII:28/01/2025 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONUCATOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAAEIdi65avx+fXSlDAAAAAQOLMA0GCSq:
Sib3DQEBcWUAMCixIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTI0MDEyNTEzMzNlNloXDTI3MDEyNTEyNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAAEIdijjVd7aJ5r0rAAAAAQOKMA0GCSqG:
Sib3DQEBcWUAMCixIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzNlNVoXDTI3MDEyNTEyNDMzNVowgAMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONUCATOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
-----:

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





## 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. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDDMD2X329

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

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московей, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDDMD2X329

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 MOLDDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

## **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>Alexandr Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

## SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice

Forma de proprietate: 16, Proprietate colectivă

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: +37322808719

WEB:

E-mail: zmii13@mail.ru

Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 10 persoane.

Persoanele responsabile de semnarea situațiilor financiare\* Nasedchin Alexandr

Unitatea de măsură: leu

### BILANȚUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	<b>A C T I V</b>			
A.	<b>ACTIVE IMOBILIZATE</b>			
	<b>I. Imobilizări necorporale</b>			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:			
	2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		

2.4. alte immobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru immobilizări necorporale	040		
<b>Total immobilizări necorporale</b> (rd.010 + rd.020 + rd.030 + rd.040)	050		
<b>II. Immobilizări corporale</b>			
1. Immobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3384131	4438372
din care:			
3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3363063	4423127
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085	21068	15245
3.6. alte mijloace fixe	086		
4. Resurse minerale	090		
5. Active biologice immobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru immobilizări corporale	120	5250844	2337159
<b>Total immobilizări corporale</b> (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	8634975	6775531
<b>III. Investiții financiare pe termen lung</b>			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care:			
2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
2.2. împrumuturi acordate părților afiliate	152		
2.3. împrumuturi acordate aferente intereselor de participare	153		
2.4. alte investiții financiare	154		
<b>Total investiții financiare pe termen lung</b> (rd.140 + rd.150)	160		
<b>IV. Creanțe pe termen lung și alte active immobilizate</b>			
1. Creanțe comerciale pe termen lung	170		
2. Creanțe ale părților afiliate pe termen lung	180		
inclusiv: creanțe aferente intereselor de participare	181		
3. Alte creanțe pe termen lung	190		

	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	<b>Total creanțe pe termen lung și alte active imobilizate</b> (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	<b>TOTAL ACTIVE IMOBILIZATE</b> (rd.050 + rd.130 + rd.160 + rd.220)	230	8634975	6775531
B.	<b>ACTIVE CIRCULANTE</b>			
	<b>I. Stocuri</b>			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	13899	24776
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11123640	11490033
	5. Avansuri acordate pentru stocuri	280		
	<b>Total stocuri</b> (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11137539	11514809
	<b>II. Creanțe curente și alte active circulante</b>			
	1. Creanțe comerciale curente	300	4552459	2646694
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	27696	45618
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2268111	2251145
	<b>Total creanțe curente și alte active circulante</b> (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6848266	4943457
	<b>III. Investiții financiare curente</b>			
	1. Investiții financiare curente în părți nefiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	<b>Total investiții financiare curente</b> (rd.380 + rd.390)	400		
	<b>IV. Numerar și documente bănești</b>	410	10281443	27361722
	<b>TOTAL ACTIVE CIRCULANTE</b> (rd.290 + rd.370 + rd.400 + rd.410)	420	28267248	43819988



	<b>TOTAL ACTIVE</b> (rd.230 + rd.420)	430	36902223	50595519
	<b>P A S I V</b>			
	<b>CAPITAL PROPRIU</b>			
	<b>I. Capital social și neînregistrat</b>			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	<b>Total capital social și neînregistrat</b> (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	<b>II. Prime de capital</b>	500		
	<b>III. Rezerve</b>			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
C.	3. Alte rezerve	530		
	<b>Total rezerve</b> (rd.510 + rd.520 + rd.530)	540		
	<b>IV. Profit (pierdere)</b>			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	35876971	29813141
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	18618853
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	<b>Total profit (pierdere)</b> (rd.550 + rd.560 + rd.570 + rd.580)	590	35876971	48431994
	<b>V. Rezerve din reevaluare</b>	600		
	<b>VI. Alte elemente de capital propriu</b>	610		
	<b>TOTAL CAPITAL PROPRIU</b> (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	35882371	48437394
D.	<b>DATORII PE TERMEN LUNG</b>			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	<b>TOTAL DATORII PE TERMEN LUNG</b> (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	<b>DATORII CURENTE</b>			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		
	din care:			
	2.1. Împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	5266	59765
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	143160	273711
	6. Datorii față de personal	760	866	
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	831429	1766706
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	39131	57943
	<b>TOTAL DATORII CURENTE</b> (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	1019852	2158125
	<b>PROVIZIOANE</b>			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
F.	4. Alte provizioane	860		
	<b>TOTAL PROVIZIOANE</b> (rd.830 + rd.840 + rd.850 + rd.860)	870		
	<b>TOTAL PASIVE</b> (rd.620 + rd.700 + rd.820 + rd.870)	880	36902223	50595519

## SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
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		<b>precedenta</b>	<b>curenta</b>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
Venituri din vânzări, total	010	40621876	58891757
din care:			
venituri din vânzarea produselor și mărfurilor	011	39203671	57105542
venituri din prestarea serviciilor și executarea lucrărilor	012	1390733	1771148
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	27472	15067
Costul vânzărilor, total	020	22086174	32917436
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	21991682	32793096
costul serviciilor prestate și lucrărilor executate terților	022	92356	124340
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026	2136	
<b>Profit brut (pierdere brută) (rd.010 - rd.020)</b>	030	18535702	25974321
Alte venituri din activitatea operațională	040	128694	829270
Cheltuieli de distribuire	050	15271	4167
Cheltuieli administrative	060	3076978	3996115
Alte cheltuieli din activitatea operațională	070	1325483	879808
<b>Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)</b>	080	14246664	21923501
Venituri financiare, total	090	1530710	1070406
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	250190	337916
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	1280520	732490

Cheltuieli financiare, total	100	512939	1786338
din care:	101		
cheltuieli privind dobânzile			
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	512939	1786338
<b>Rezultatul: profit (pierdere) financiar(ă)</b> (rd.090 - rd.100)	110	1017771	-715932
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
<b>Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere)</b> (rd.120 - rd.130)	140		
<b>Rezultatul din alte activități: profit (pierdere)</b> (rd.110 + rd.140)	150	1017771	-715932
<b>Profit (pierdere) pînă la impozitare</b> (rd.080 + rd.150)	160	15264435	21207569
Cheltuieli privind impozitul pe venit	170	1872862	2588716
<b>Profit net (pierdere netă) al perioadei de gestiune</b> (rd.160 - rd.170)	180	13391573	18618853

## SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
	<b>Capital social și neînregistrat</b>					
	1. Capital social	010				
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
I.	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	<b>Total capital social și neînregistrat</b> (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	<b>Prime de capital</b>	070				
III.	<b>Rezerve</b>					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

	3. Alte rezerve	100				
	<b>Total rezerve</b> (rd.080 + rd.090 + rd.100)	110				
	<b>Profit (pierdere)</b>					
IV.	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	(	(	(
	<b>Total profit (pierdere)</b> (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	<b>Rezerve din reevaluare</b>	170				
VI.	<b>Alte elemente de capital propriu</b>	180				
	<b>Total capital propriu</b> (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

## SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
<b>Fluxuri de numerar din activitatea operațională</b>			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
<b>Fluxul net de numerar din activitatea operațională</b> (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
<b>Fluxuri de numerar din activitatea de investiții</b>			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		

Alte încasări (plăți)	130		
<b>Fluxul net de numerar din activitatea de investiții</b> (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
<b>Fluxuri de numerar din activitatea financiară</b>			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
<b>Fluxul net de numerar din activitatea financiară</b> (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
<b>Fluxul net de numerar total</b> (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
<b>Sold de numerar la începutul perioadei de gestiune</b>	230		
<b>Sold de numerar la sfârșitul perioadei de gestiune</b> (± rd.210 ± rd.220 + rd.230)	240		

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

## Recipisa

Respondent

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

A prezentat raportul: RSF1\_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 26.03.2024 17:05:42

## Recipisa 2

Respondent

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

A prezentat raportul: RSF1\_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 09.04.2024 09:26:11

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.



## Date generale despre ofertant

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<b>Banca:</b> BC "Moldindconbank" S.A. fil. Invest
<b>Codul băncii:</b> MOLDMD2X329
<b>Cod fiscal:</b> 1010600028048
<b>Cod TVA:</b> 0607490

Cu respect,

Vitalie Poiata

Administrator



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

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

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<b>PRODUCT NAME</b>	<b>CODE</b>
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

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

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<b>PRODUCT NAME</b>	<b>CODE</b>
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
<b>CLINICAL CHEMISTRY - INSTRUMENTS</b>	
A15	83105
A25	83101
BA400	83400
BA200	83200
BTS-350	80175
<b>CONSUMABLES (INSTRUMENTS)</b>	
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
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY - REAGENTS AUTOMATED SYSTEMS A15/A25</b>	
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
<b>CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL</b>	
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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<b>PRODUCT NAME</b>	<b>CODE</b>
RHEUMATOID CONTROL SERUM I	31213
RHEUMATOID CONTROL SERUM	31214
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE)</b>	
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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<b>PRODUCT NAME</b>	<b>CODE</b>
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
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS</b>	
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

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

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

P-6.1.

# BIOSYSTEMS



BioSystems S.A., organizer of the training, CERTIFIES that

***Mr. Nasedchin Alexandr***

successfully participated in the service engineer's training  
"Random Access Biochemistry Analyzer A15, A25"

Director of technical service department  
Representative office "BioSystems S.A. **Russia**"

Sergey Vasiliyev



# BIOSYSTEMS



BioSystems S.A., organizer of the training, CERTIFIES that

**Mr. Poiata Vitalie**

successfully participated in the service engineer's training  
"Random Access Biochemistry Analyzer A25"

Director of technical service department  
Representative office "BioSystems S.A." Russia

Sergey Vasiliyev





Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARAȚIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.



**Xavier Palomar**  
Area Manager  
27-April-2011



# Declaration of Conformity **CE**

**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Mindray Building, Keji 12th Road South, High-tech  
Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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

**Product:** Auto Hematology Analyzer

**Model:** BC-760[B], BC-760[R], BC-780[R]

**Classification:** The device not in IVDD annex II and not for self testing/performance  
evaluation

**Conformity Assessment Route:** IVDD Annex III (excluding Section 6)

GMDN: 35476

We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

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

**Start of CE-Marking:** 2022-3-30  
**Place, Date of Issue:** 2022-3-30

**Signature:**   
**Name of Authorized Signatory:** Mr. WangXinBing  
**Position Held in Company:** Deputy Director, Technical Regulation Department



Declaration of Conformity V 1.0

## Applied Standards List

<b>Product:</b>	<b>Auto Hematology Analyzer BC-760[B], BC-760[R], BC-780[R]</b>
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**Applied Standards:**

EN ISO 18113-1:2011		In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011		In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016		Graphical symbols for use in the labelling of medical devices
EN 13612: 2002		Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2019		Medical devices - Application of risk management to medical devices
EN 61010-1:2010+A1:2019		Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2020	IEC	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018		Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-010:2020	IEC	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2013		Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013		Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2015		Medical device software- Software life cycle processes
IEC 62366-1: 2015		Medical devices — Application of usability engineering to medical devices
EN IEC 63000: 2018		Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances



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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 12<sup>th</sup> 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).

**Classification:** The device not in IVDD annex II and not for self testing/performance evaluation

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

**Products:** Attachment I

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

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

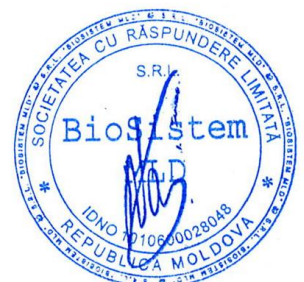
Place, Date Of Issue : Shenzhen, 2016-09-01



**Signatory name:** Chuanbin Tan

**signatory title:** Technical Regulation Manager

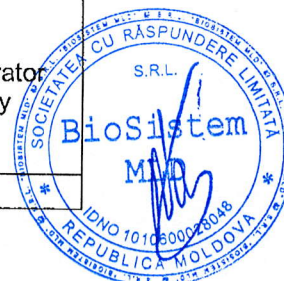
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**



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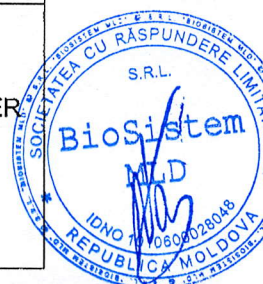
**ATTACHMENT I**

Product Name	Product Model	Accessories
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 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、	M-50D DILUENT



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	BC-5200	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
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



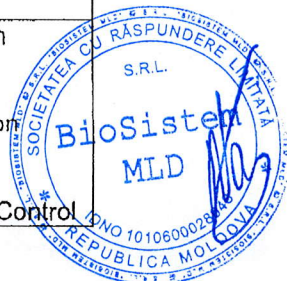
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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology 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 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 BR60 Hematology Control
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



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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、 HM-500X	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
Urine Analyzer	UA-66、 UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、 BC-21s、 BC-30s、 BC-31s、 HM-200X	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





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		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	/	/
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	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
Chemistry Analyzer	BS-400、BS-420	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 cuvettes



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		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	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
Chemistry Analyzer	BS-380、BS-390	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 Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode



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		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
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、 BS-180	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-200、BS-220	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



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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
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 System (RMS)



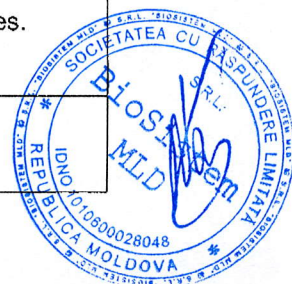
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Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine 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
Chemistry Analyzer	BS-480、BS-490	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 Built-in sample/reagent bar code reader Remote management system (RMS) Water supply module External air pump
Chemistry Analyzer	BS-430、BS-450、 BS-460	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode



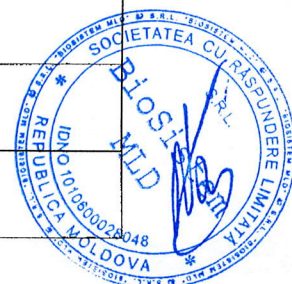
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		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	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 reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、 CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、 CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
$\alpha$ -Amylase ( $\alpha$ -AMY) Kit (IFCC Method)	/	/



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Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/
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)	/	/
$\alpha$ -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)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/





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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)	/	/
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)	/	/



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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	/	/
Multimun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
$\alpha$ -L-Fucosidase Kit (CNPf method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
$\beta$ 2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/



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CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β2-MG Calibrator	/	/
β2-MG Control	/	/
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)	/	/
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 β HCG Calibrators	/	/



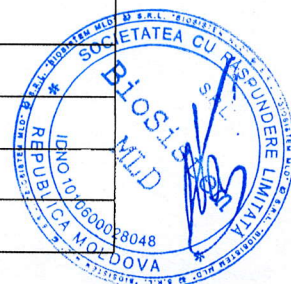
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Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen (CLIA)	/	/
Alpha-fetoprotein (CLIA)	/	/
Cancer Antigen 125 (CLIA)	/	/
Cancer Antigen 15-3 (CLIA)	/	/
Carbohydrate Antigen 19-9 (CLIA)	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin (CLIA)	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" (ASO) Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C (CysC) Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein (FR-CRP) Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor (RF) Kit(Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
$\beta$ 2-Microglobulin ( $\beta$ 2-MG) Kit (Latex Immunoturbidimetric Method)	/	/
$\beta$ 2-Microglobulin Control	/	/
$\beta$ 2-Microglobulin Calibrator (for Serum)	/	/
$\beta$ 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/



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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)	/	/
$\beta$ -Hydroxybutyrate ( $\beta$ -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	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
$\beta$ -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
$\beta$ -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I (CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide (CLIA)	/	/
BNP Calibrators	/	/
Myoglobin (CLIA)	/	/
MYO Calibrators	/	/



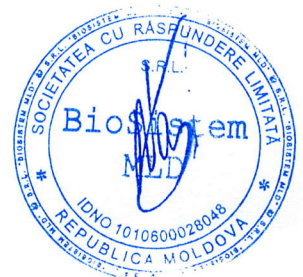
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Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotropic hormone(CLIA)	/	/
ACTH Calibrators	/	/
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 (level 1)	/	/
ClinChem Multi Control (level 2)	/	/
Sample Diluent	/	/
HCY Control	/	/
Homocysteine (HCY) Kit (Enzymatic Cycling Method)	/	/
Total Protein in Urine/CSF(TPUC) Kit (Pyrogallol Red-Molybdate Method)	/	/
TPUC Control	/	/
25-OH-Vitamin D Total (CLIA)	/	/



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25-OH-Vitamin D Total Calibrators	/	/
Parathyroid hormone (CLIA)	/	/
PTH Calibrators	/	/
Calcitonin (CLIA)	/	/
Calcitonin Calibrators	/	/
Folate(CLIA)	/	/
Folate Calibrators	/	/
Vitamin B12(CLIA)	/	/
Vitamin B12 Calibrators	/	/
Metabolic Multi Control	/	/
Red Blood Cell Folate Releasing Reagent	/	/
Cancer Antigen 72-4 (CLIA)	/	/
Neuron-specific enolase (CLIA)	/	/
CYFRA 21-1 (CLIA)	/	/
Antibody to Treponema pallidum (CLIA)	/	/
CA72-4 Calibrators	/	/
Cyfra21-1 Calibrators	/	/
Anti-TP Calibrators	/	/
NSE Calibrators	/	/
Tumor Marker Multi Control	/	/
NSE Control	/	/
Anti-TP Control	/	/



December 29<sup>th</sup>, 2020

## LETTER OF DECLARATION

To whom it may concern,

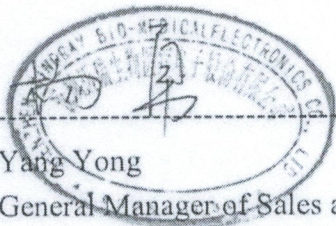
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("Mindray")  
manufacturer of Hematology analyzer **BC-30s**, do hereby declare that:

The following reagents:

- A12-000047 M-30D DILUENT
- A12-000084 M-30CFL LYSE
- 105-000405-00 Probe Cleanser
- 105-003223-00 SC-CAL PLUS Calibrator 2×3.0ml
- 105-003227-00 BC-3D Control 3 x 3.0ml Tri-pack(1L, 1N, 1H)

Are manufactured by our company exclusively for the use with the closed-system BC-30s  
Hematology Analyzers.

Sincerely yours,



Yang Yong

General Manager of Sales and Marketing Division, CIS & TUR  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**



## Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

### Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.



## Сертификат

Poiata Vitalie

компания: SRL Biosistem MLD

### Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
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