

ORDIN DE PLATĂ		Nr.	690	DATA EMITERII	6 ianuarie 2026	TIP.DOC.1
PLĂTIȚI:	35 000-00	LEI	Treizeci si cinci mii lei 00 bani			
PLĂTITOR: (R) BIOSISTEM MLD SRL		CODUL IBAN		MD95ML000000002251429243		
		CODUL FISCAL		1010600028048		
PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.						
BENEFICIAR: (R) I.M.S.P. Spitalul Clinic Republican Timofei Mosneaga		CODUL IBAN		MD57MO2251ASV96476607100		
		CODUL FISCAL		1003600150783		
PRESTATORUL BENEFICIAR: OTP Bank S.A.						
DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achiziție publica nr. ocds-b3wdp1-MD-1765473577480 din 12.01.2026				TIPUL TRANSFERULUI NORMAL/URGENT		
				N L.Ș.		
CODUL TRANZACȚIEI	DATA PRIMIRII	DATA EXECUTĂRII		LAZAR ANNA		
001				LAZAR ANNA		
Document transmis prin instrument de plată electronic cu acces la				SEMNĂTURILE EMITENTULUI		
la distanță de tip internet-banking				SEMNĂTURA PRESTATORULUI		
				L.Ș.		
MOTIVUL REFUZULUI						
Nota: Responsabilitatea privind veridicitatea și corectitudinea informației indicate în ordinul de plată îi revine emitentului*						
*Regulamentul cu privire la transferul de credit, debitarea directă și atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023						



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

0948048

Din
От

29.12.2025 09:48



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

BIOSISTEM MLD



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

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

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

13.01.2026 09:48



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

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 29.12.2025 09:48

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

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



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

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

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “**legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător**”, cu modificarile ulterior adoptate de parlamentul RM, **Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale** nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2024 - 31.12.2024

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
	A C T I V			
A.	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	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 imobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru imobilizări necorporale	040		
Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Imobilizări corporale			
1. Imobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	4438372	7706354
din care:	081		
3.1. clădiri			
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	4423127	6955543
3.4. mijloace de transport	084		629606
3.5. inventar și mobilier	085	15245	9423
3.6. alte mijloace fixe	086		111782
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	2337159	1435404
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	6775531	9141758
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care:	151		
2.1. acțiuni și cote de participație deținute în părțile afiliate			
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanțe pe termen lung și alte active imobilizate			
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		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	6775531	9141758
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	24776	1133
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11490033	15684462
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11514809	15685595
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2646694	4561951
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	45618	25303
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2251145	3491833
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	4943457	8079087
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	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		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	27361722	35607750
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	43819988	59372432

	TOTAL ACTIVE (rd.230 + rd.420)	430	50595519	68514190
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	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		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	48431994	40453271
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	25286521
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	48431994	65739792
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	48437394	65745192
C.				
	DATORII PE TERMEN LUNG			
	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		
D.				

	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		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
E.	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		
	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	59765	10312
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	273711	151820
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	1766706	2601490
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	57943	5376
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2158125	2768998
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientșilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	50595519	68514190

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2024 până la 31.12.2024

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
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		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	58891757	72234217
din care:			
venituri din vânzarea produselor și mărfurilor	011	57105542	70297293
venituri din prestarea serviciilor și executarea lucrărilor	012	1771148	1701254
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	15067	235670
Costul vânzărilor, total	020	32917436	37551083
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	32793096	37420276
costul serviciilor prestate și lucrărilor executate terților	022	124340	130807
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	25974321	34683134
Alte venituri din activitatea operațională	040	829270	1999137
Cheltuieli de distribuire	050	4167	
Cheltuieli administrative	060	3996115	6021871
Alte cheltuieli din activitatea operațională	070	879808	692169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	21923501	29968231
Venituri financiare, total	090	1070406	970167
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	337916	255488
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	732490	714679

Cheltuieli financiare, total	100	1786338	2592418
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	1786338	2592418
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-715932	-1622251
Venituri cu active imobilizate și excepționale	120		836616
Cheltuieli cu active imobilizate și excepționale	130		409025
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		427591
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-715932	-1194660
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	21207569	28773571
Cheltuieli privind impozitul pe venit	170	2588716	3487050
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	18618853	25286521

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
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	Profit (pierdere)					
	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	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR
de la până la

Anexa 4

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

Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
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		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

BIOSISTEM.PDF

Объяснительная записка

SRL "Biosistem MLD"

Информация о соответствии финансовых отчетов национальным стандартам бухгалтерского учета

Финансовые отчеты составлены в соответствии с положениями Национальных стандартов бухгалтерского учета. Отклонения от основополагающих принципов и качественных характеристик, предусмотренных в национальных стандартах бухгалтерского учета, не были допущены.

Раскрытие учетных политик

Показатели финансовых отчетов были рассчитаны на основе методов и способов, предусмотренных в учетных политиках, утвержденных приказом директора субъекта № 3 от 30 декабря 2014 года. В течение отчетного периода в учетных политиках не было изменений.

Анализ экономико-финансовой деятельности SRL "Biosistem MLD" в 2024 году

Анализ доходов от продаж

ТАБЛИЦА АНАЛИЗА РЕНТАБЕЛЬНОСТИ АКТИВОВ. ПОКАЗАТЕЛИ

1. Общая прибыль	34683134
2. Объем продаж	72234217
3. Всего активов	68514190
4. Возвратность активов	1.05
5. Прибыльность продаж	48
6. Рентабельность активов	50.62

Величина доходов от продаж SRL "Biosistem MLD" в 2024 г. составила 72234.2 тыс. леев, что на 13342.46 тыс. леев больше, чем в предыдущем отчетном периоде. Операционная деятельность предприятия включает один вид деятельности - продажа (биохимические реактивы).

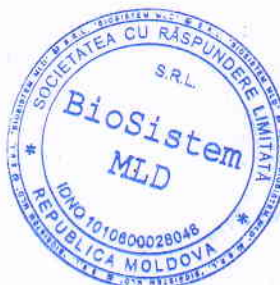
Анализ финансовых результатов и рентабельности

ТАБЛИЦА АНАЛИЗА ЭКОНОМИЧЕСКОЙ РЕНТАБЕЛЬНОСТИ ПОКАЗАТЕЛИ

1. Общая прибыль	34683134
2. Чистая прибыль	28773571
3. Собственный капитал	65745192
4. Постоянный капитал	5400
5. Уд. вес собственного капитала в постоянном капитале	1217503.5
6. Соот. общей прибыли к чистой прибыли	1.2
7. Финансовая рентабельность	43.77
8. Экономическая рентабельность	642280

В 2024 г. SRL "Biosistem MLD" получило прибыль в размере 25286.52 тыс. леев, что на 6667.67 тыс. леев больше, чем в предыдущем отчетном периоде. Это увеличение прибыли обусловлено ростом прибыли по курсовой разнице и прочих доходов.

Директор SRL "Biosistem MLD"



Poata Vitalii.

Recipisa

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2024

Data prezentarii: 01.04.2025

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 01.04.2025 16:19:29

Recipisa 2

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscală: A/2024

Data prezentării: 01.04.2025

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 02.04.2025 16:10:17

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.

EC DECLARATION OF CONFORMITY *DECLARACIÓN CE DE CONFORMIDAD*

BioSystems SA, a company established in
Costa Brava 30, 08030 Barcelona, Spain,

*BioSystems SA, compañía establecida en
c/Costa Brava 30, 08030 Barcelona, España,*

Declares under its responsibility that the
BioSystems product dedicated to the random
access analysers A15 and A25

*Declara bajo su responsabilidad que el
producto BioSystems dedicado a los
analizadores automáticos random access A15
y A25*

CERULOPLASMIN

Cod.: 13340

meets the applicable provisions of the
**Directive 98/79/EC on in Vitro Diagnostic
Medical Devices** under the specifications
declared by BioSystems SA.

*cumple las disposiciones aplicables de la
Directiva 98/79/CE sobre Productos
Sanitarios para Diagnóstico in Vitro, bajo
las especificaciones declaradas por
BioSystems, S.A.*

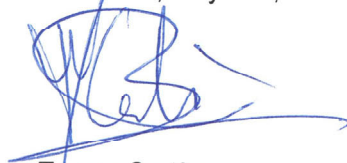
It means that the product:

Esto significa que el producto:

- 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.

- *cumple con los Requisitos Esenciales aplicables según lo establecido en el Anexo I, y su documentación técnica se realiza siguiendo los requisitos del Anexo III*
- *está clasificado como Otros Productos (todos los productos excepto los del Anexo II y para Autodiagnóstico), por ello la evaluación de la conformidad sigue el procedimiento indicado en el Anexo III de la Directiva, sin requerir la intervención de un Organismo Notificado*

Barcelona, May 25th, 2022



Teresa Cortès
CQO



Pau Vila Cases
CEO

BC-5150

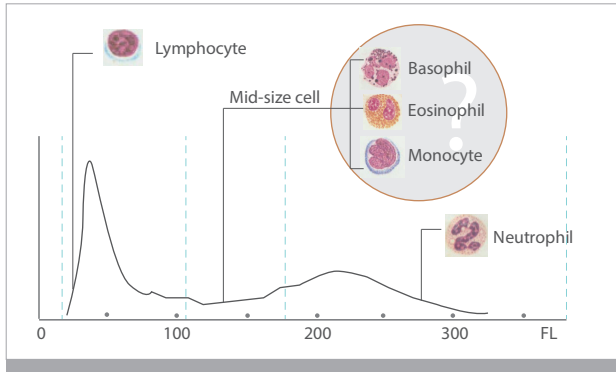
Auto Hematology Analyzer

A "CUTE" 5-part



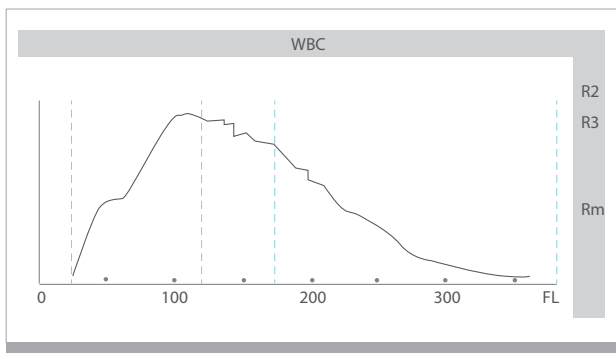
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



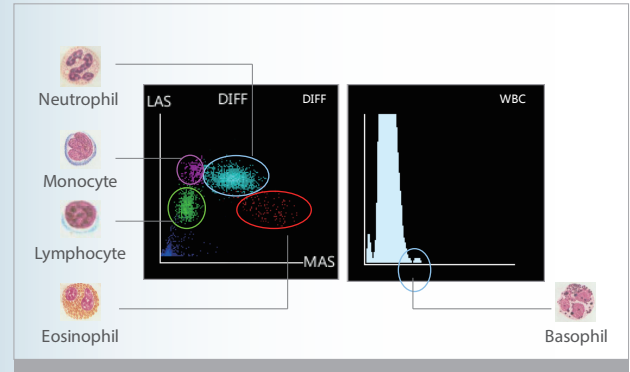
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

Flag information: 3-part



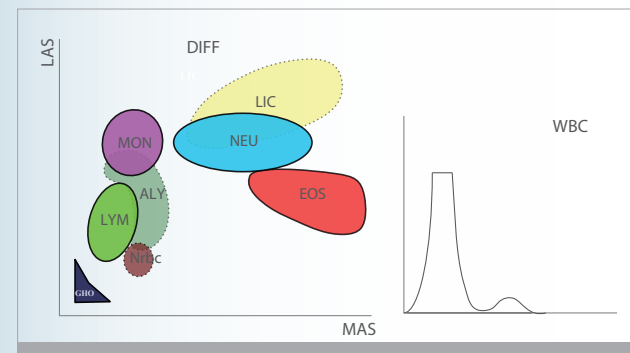
WBC histogram only indicates regional abnormal graph, it can't bring specific flags for different clinical cases.

WBC differential: 5-part



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

Flag information: 5-part



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



Dr Marisela Ramos, lab manager

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

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

BC-5150

Auto Hematology Analyzer

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

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

WBC 5-part differentiation, 25 reportable parameters and 12 research parameters, 3 histograms and 3 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

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

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

10.4 inch large TFT touch screen with user-friendly software

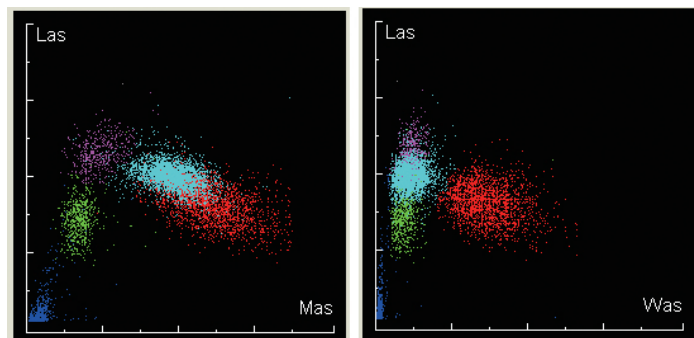
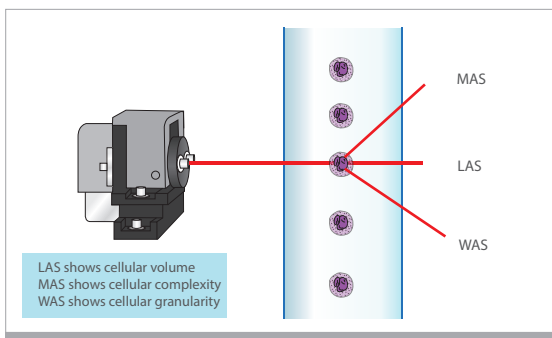
Large storage capacity: up to 250,000 samples

Throughput: 60 samples per hour

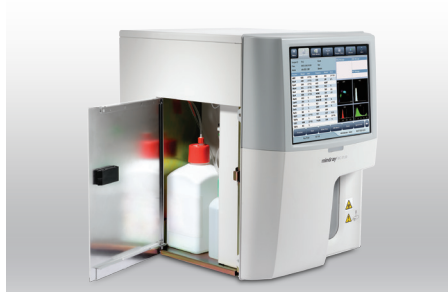
Sample volume is only 15 μ L which is ideal for pediatrics



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



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



Compact

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



Utility

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



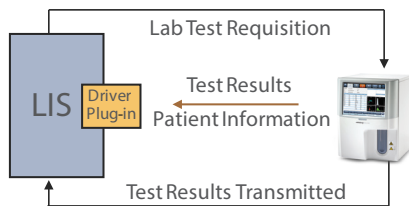
BC-5150 inherits its convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.



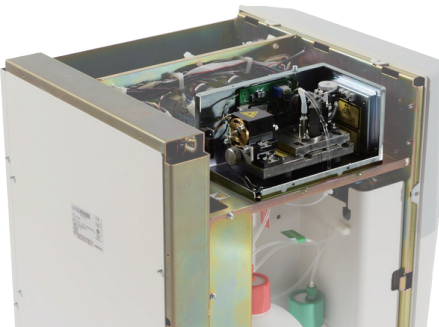
Running capillary blood through the sample probe directly is more convenient for the users in children's hospitals, etc. For Prediluted mode, BC-5150 has higher dilution ratio than other 5-part hematology analyzers, thus it brings a better mixing effect.



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

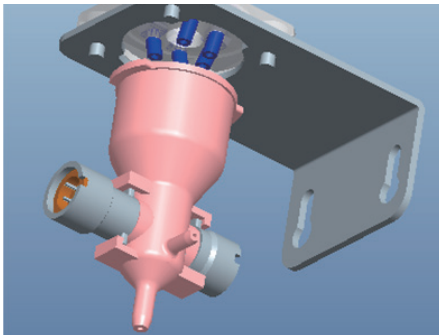


BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.



Technology

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



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



Efficient

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

Technical Specifications

Principles

Impedance method for RBC and PLT counting

Cyanide free reagent for hemoglobin test

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

Parameters

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

12 research parameters including LIC%, LIC#, ALY%, ALY#, PLT Clumps#, PLT Clumps%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%

3 histograms for WBC, RBC and PLT

3 scattergrams for WBC differential

Reagent

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

Performance

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

Sample Volume

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

Throughput

60 samples per hour

Display

10.4 inch TFT Touch Screen

Multi-language

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

Data Storage Capacity

Up to 250,000 results including numeric and graphical information

Communication

LAN port supports HL7 protocol

Interface

USB, LAN

Support bi-directional LIS

Printout

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

Operating Environment

Temperature: 10°C~30°C

Humidity: 20%~85%

Air pressure: 70 kPa~106 kPa

Power requirement

100V-240V

50Hz/60Hz

Dimension and Weight

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

Weight :24kg

BS-620M

Биохимический анализатор

mindray

Технические характеристики

Функционал системы:

Производительность: 600 фотометрических тестов в час, до 800 тестов в час с ISE модулем

Принципы измерений: Абсорбционная фотометрия, турбидиметрия

Методы анализа: до 77 фотометрических тестов + 3 ISE электрода + 3 сывороточных индекса

Методики: Конечная точка, фиксированное время, кинетика, ISE

Работа с образцами:

SDM: 120 образцов на 12 штативах, непрерывная загрузка образцов, приоритетная подача срочных образцов

Объем образца: 1,5–45 мкл с шагом 0,1 мкл

Образец HbA1c: Цельная кровь для анализа на HbA1c

Пробозаборник: Определение уровня жидкости, определение сгустков, защита от столкновений

Работа с реагентами:

Лоток для реагентов: 80 позиций с системой охлаждения (2–8°C)

Объем реагента: 10–200 мкл с шагом 0,5 мкл

Зонд для реагентов: Определение уровня жидкости, определение пузырьков, защита от столкновений

Встроенное устройство считывания штрих-кодов:

Устройства считывания штрих-кодов с образцов и реагентов поддерживают такие системы кодирования, как Codabar, ITF (2 из 5 чередующийся), Code 128, Code 39, UPC/EAN и Code 93; Может обмениваться данными с ЛИС в двунаправленном режиме

Реакционная система:

Реакционный объем: 70–300 мкл

Температура реакции: 37°C с колебанием температуры 0,1°C

Реакционные кюветы: 124 кюветы многократного использования с

8-ступенчатой автоматической промывкой

Оптическая система:

Источник света: Галоген-вольфрамовая лампа

Фотометр: Фотометр с дифракционной решеткой

Длина волны: 16 длин волн (340 нм, 380 нм, 412 нм, 450 нм, 480 нм, 505 нм, 546 нм, 570 нм, 605 нм, 630 нм, 660 нм, 700 нм, 740 нм, 770 нм, 800 нм, 850 нм)

Диапазон поглощения: 0–3,5 коэф (конверсия 10 мм)

Контроль и калибровка:

Режим калибровки: Линейная (одноточечная, двухточечная и многоточечная), Logit-Log 4P, Logit-Log 5P, Сплайн, экспоненциальная, полиномиальная, параболическая

Правила контроля качества: Система правил Вестгарда, Twin plot

Операционный блок:

Операционная система: Сенсорный экран (дополнительно), Windows 10 (64 бит)

Интерфейс: RS-232, сетевой порт, USB/параллельный порт

Условия эксплуатации:

Источник питания: 200–240 В, 50/60 Гц, 1700 В-А или 110/115 В, 60 Гц, 1700 В-А

Температура: 15–30°C

Относительная влажность: 35–85 %

Размеры: 1380 мм (длина)*860 мм (ширина)*1200 мм (высота)

Вес: 350 кг



www.mindray.com

№ изделия: RU-BS-620M-210285X8P-20220902
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mindray

Качественное медицинское обслуживание для всех

BS-620M

Биохимический анализатор

Мощный и эффективный



BS-620M

Мощный и эффективный



Гибкое управление образцами

- Перемещение партии образцов
- Непрерывная загрузка образцов на штативы
- Приоритетная подача срочных образцов (STAT-образцов)
- Незамедлительный повторный анализ



Анализ цельной крови на гликированный гемоглобин (HbA1c)

- Сертификация согласно NGSP и прослеживаемость согласно IFCC
 - Встроенный гемолиз без подготовки образцов
- Значительная интерференция вариантов гемоглобина отсутствует
 - Более низкий предел обнаружения гемоглобина, снижение количества повторных анализов



Интегрированный ионоселективный модуль

- 1 пробирка для крови для выполнения анализов на электролиты и биохимических анализов фотометрическими методами
- Длительный срок службы ионоселективных электродов
- Простота эксплуатации и технического обслуживания



Надежная система тестирования

- Отличные показатели сигматрии мирового уровня при использовании оригинальных реагентов
- Интеллектуальное обнаружение аномальных реакций, сигнализация и автоматический повтор анализа для минимизации ошибочных результатов

Небольшая
занимаемая
площадь:

1,2 м²

600 фотометрических
тестов в час, до 800
тестов в час cISE
модулем



Анализ цельной крови на гликированный гемоглобин (HbA1c)



Встроенный гемолиз образцов цельной крови для повышения эффективности работы

Предварительная обработка без вмешательства оператора для снижения риска биологического загрязнения и вероятности ошибок, связанных с человеческим фактором

120 тестов/час при исследовании на HbA1c для сокращения времени выполнения анализа

Гибкое управление образцами

Непрерывная загрузка образцов

Непрерывная загрузка образцов на штативы
До 120 позиций для образцов
Увеличение времени работы без участия оператора

Быстрый запуск для повторного анализа образцов

Автоматический запуск для анализа образцов
Автоматическая приоритетная подача срочных образцов и повторный анализ

Приоритетная подача срочных образцов (STAT-образцов)

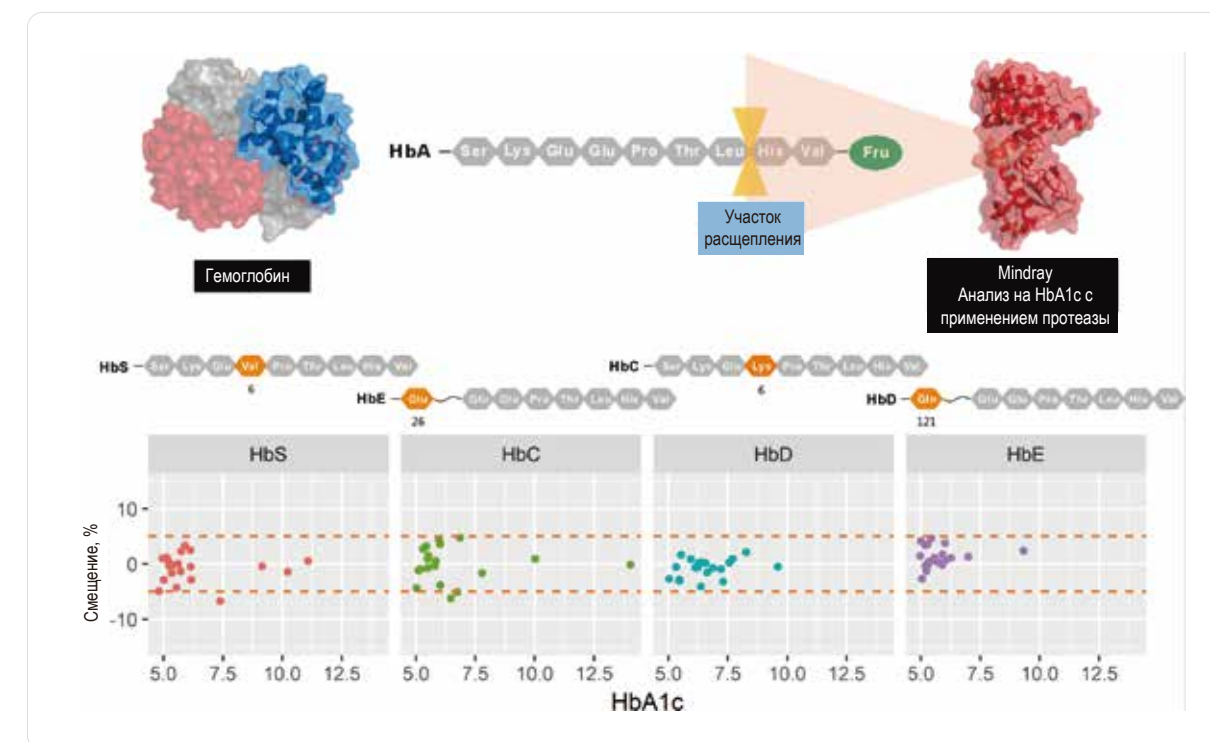
Выделенная позиция для срочных образцов,
аспирация 1 минута
Быстрый отчет о результатах ISE+CO2 за 7 минут



Интеллектуальное разбавление

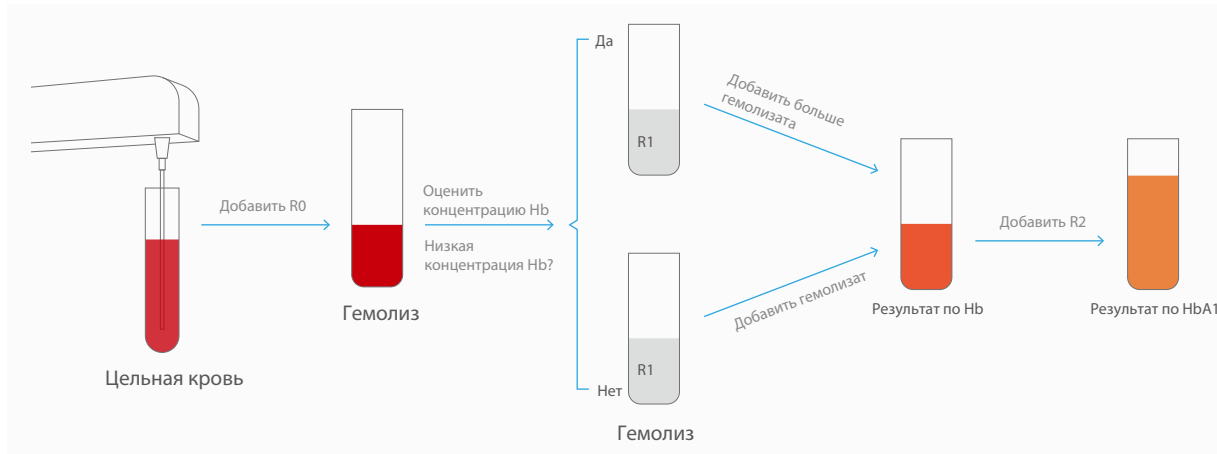
Запатентованная функция интеллектуального разбавления
Оперативное получение результатов

Благодаря реагенту HbA1c компании Mindray при использовании ферментативного метода анализа можно точно определять гликированные N-концевые аминокислоты из бета-цепей гемоглобина, что позволяет эффективным образом избежать интерференции вариантов гемоглобина (HbS, HbC, HbE и HbD) и других производных гемоглобина (лабильный HbA1c, карбамилированный Hb и ацетилованный Hb). Ферментативный метод анализа на гликированный гемоглобин (HbA1c) компании Mindray дает надежные и экономически эффективные результаты с самого первого измерения и сокращает количество последующих подтверждающих исследований.



Нижний предел обнаружения гемоглобина для анализа на HbA1c

Выполняется оценка концентрации гемоглобина в процессе гемолиза и заблаговременное начало тестов на увеличение концентрации в образцах с низкой концентрацией гемоглобина. Данная функция позволяет понизить предел обнаружения и расширить линейную область определения концентрации гемоглобина с целью уменьшения количества повторных тестов и снижения отходов реагентов при анализе образцов с признаками анемии.



Интегрированный ионоселективный модуль

Встроенный ионоселективный модуль

- Выдача результатов по Na^+ , K^+ , Cl^-
- 1 пробирка для крови для выполнения анализов на электролиты и биохимических анализов фотометрическими методами

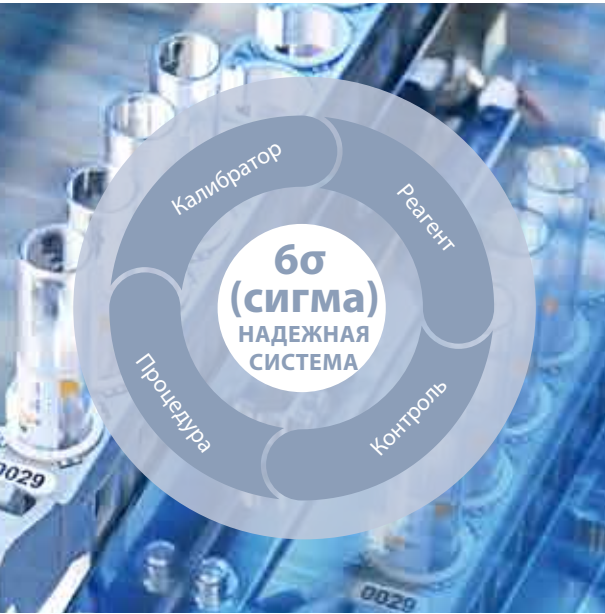


Эффективное и простое управление

- До 300 тестов в час
- Срок службы электродов Na/K/референтных электродов до 9 месяцев
- Автоматическая калибровка
- Малый расход
- Простота эксплуатации и технического обслуживания



Надежная система тестирования



Высокий уровень показателей сигмаметрии

Оригинальные реагенты и утвержденный протокол применения снижают процент неточностей и погрешностей, что способствует достижению отличных показателей сигмаметрии мирового уровня. Система с более высоким показателем сигма позволяет лабораториям обеспечивать высокий уровень качества при меньших затратах, а также повышает уверенность и удовлетворенность медицинских работников.

Интеллектуальное обнаружение аномальных реакций

Мощное программное обеспечение со встроенными алгоритмами, которые могут отслеживать реакцию на наличие отклонений, подавать сигналы тревоги и запускать автоматический повтор анализа образцов, у которых наблюдаются отклонения от нормы во время тестирования, например, истощение субстрата, нехватка кислорода, хук-эффекты и пр. Такой интеллектуальный подход с функциями обнаружения, сигнализации и автоматического повтора анализа минимизирует количество ложных результатов и риск постановки неправильного диагноза, а также позволяет получить точные и надежные результаты исследований.



mindray

BS-2000 Modular System

Clinical Chemistry Solution



Mindray Clinical Chemistry Solution

High Throughput

2000 photometric tests/hour

Up to 600 tests/hour for ISE

Up to four modules integrated capability

Flexible scalability

Advanced Software

Results traceability

Reflex function

Flexible STAT & rerun

Real-time status monitoring

High Performance Instrument



BS-2000
Modular System



Original Calibrators
and Controls



Quality Management
System

Professional Service

Reliable Results

Reliable Results

- Advanced mechanical system
- Complete reference system
- Integral traceability system
- International traceability certificate

Standardization
Laboratory

Reference
Laboratory

Dedicated Chemistry
Reagents

Dedicated Reagent System

Dedicated Reagent System

- Wide panel clinical chemistry assays
- Original calibrators and controls
- Reliable performance
- ISO standard quality

BS-2000 Modular System

Reagent Carousel 2

1. 70 positions (40 outer and 30 inner) for R2 and R4
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

Probe R21 and Probe R22

1. 10µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

Probe R11 and Probe R12

1. 80µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

Reagent Carousel 1

1. 70 positions (40 outer and 30 inner) for R1 and R3
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

Reaction Carousel

1. 80µl minimum reaction volume
2. 412 glass cuvettes for permanent use
3. Direct solid heating

6-head Sample Mixer

1. Flat mixing bar with high efficiency
2. Two-step washing with pre-heated detergent and water
3. Easy replacement and maintenance

Return Lane



Indirect ISE

Low sample volume, high ISE analysis throughput, and cost-effective electrodes. Independent buffer aspiration system – buffer syringe transfers ISE reagent to mixer through ISE buffer nozzle.

Dual-needle S

1. 1.5µl-25µL, with increment of 0.5µl
2. Clog detection, bubble detection and tracking
3. Collision protection and auto recovery from collision

System Layout

ers / 6-head Reagent Mixers

iciency
heated
enance

8-stage Cuvette Wash Station

- 1. Cuvette washing with pre-heated detergent and water
- 2. Independent water blank measurement

Sample Delivery Module (SDM)

- 1. Patented double-layer & basket delivery design, up to 600 sample positions
- 2. Continuous sample loading and off loading
- 3. 5 types of racks

Sample Carousel

- 1. 140 positions for different types of sample tubes
- 2. 25 positions in cooling compartment for calibrators and controls
- 3. Flexible for STAT, rerun or other routine samples with higher priority

Individual STAT Lane

- 1. 32s quick response
- 2. One touch to initiate analysis

Sample Probe

rement of 0.1µL
ble detection, level
ing
and auto recovery

Passing Lane

- 1. Higher priority for STAT, calibrator, control and rerun racks
- 2. For routine sample racks to be transferred to other analytical unit(s)

Normal Lane

Advanced Software



User-friendly Interface

- Unified platform for BS-2000 series, BS-800 series, BS-480 and future instrument
- Real-time status monitoring of analytical unit, SDM and carousels



Real-time QC Status Monitoring

- Westgard Rules and Two-Control Evaluation check
- Levey-Jennings chart and Twin-Plot chart for review
- Real-time alarm and locating when QC result(s) is out of range
- Auto QC setup capability

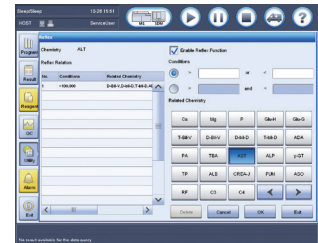
Traceable Test Results

- Reagent, calibrator and control information can be recalled from archive history
- User-friendly, intuitive software design, easy to trace results



Reflex Function

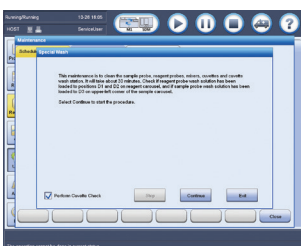
- Pre-defined reflexive assays will be performed automatically when preset criteria is met
- Each assay may involve multiple reflexive criterias
- Each criteria may initiate up to a maximum of 20 relevant assays



Test Summary	Test Date	Test Time	Test Result	Test Unit	Test Status	Test Comment
Test 1	2012-10-10	10:00	10.0	mg/dL	Pass	
Test 2	2012-10-10	10:05	10.5	mg/dL	Pass	
Test 3	2012-10-10	10:10	11.0	mg/dL	Pass	
Test 4	2012-10-10	10:15	11.5	mg/dL	Pass	
Test 5	2012-10-10	10:20	12.0	mg/dL	Pass	
Test 6	2012-10-10	10:25	12.5	mg/dL	Pass	
Test 7	2012-10-10	10:30	13.0	mg/dL	Pass	
Test 8	2012-10-10	10:35	13.5	mg/dL	Pass	
Test 9	2012-10-10	10:40	14.0	mg/dL	Pass	
Test 10	2012-10-10	10:45	14.5	mg/dL	Pass	
Test 11	2012-10-10	10:50	15.0	mg/dL	Pass	
Test 12	2012-10-10	10:55	15.5	mg/dL	Pass	
Test 13	2012-10-10	11:00	16.0	mg/dL	Pass	
Test 14	2012-10-10	11:05	16.5	mg/dL	Pass	
Test 15	2012-10-10	11:10	17.0	mg/dL	Pass	
Test 16	2012-10-10	11:15	17.5	mg/dL	Pass	
Test 17	2012-10-10	11:20	18.0	mg/dL	Pass	
Test 18	2012-10-10	11:25	18.5	mg/dL	Pass	
Test 19	2012-10-10	11:30	19.0	mg/dL	Pass	
Test 20	2012-10-10	11:35	19.5	mg/dL	Pass	

Test Summary

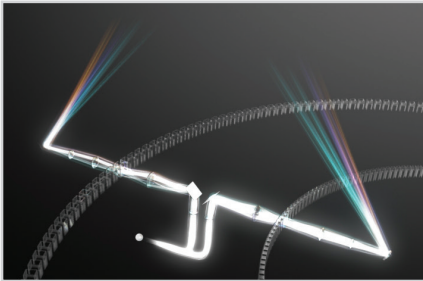
- Test summary during certain period, including calibration, QC, sample, valid tests and rerun tests
- Facilitate to computation of total test costs within a defined period
- The summary can be archived into excel files or printed for review and backup



Step-by-step Maintenance Guide

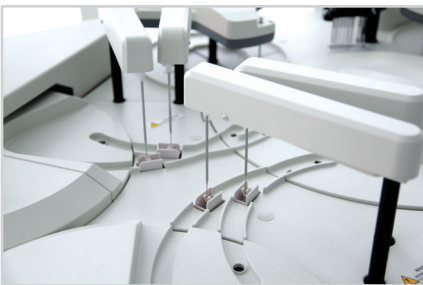
- Scheduled maintenance and maintenance guide for chemistries and ISE
- Ensure performance reliability and reduce unnecessary service calls
- Error report transferrable to service engineers for immediate troubleshooting; minimize instrument downtime

Reliable Results



Enhanced Optical System

- Dual-optical system with same light source
- Dual-lens and dual-diaphragm technology
- 80 μ l minimum reaction volume

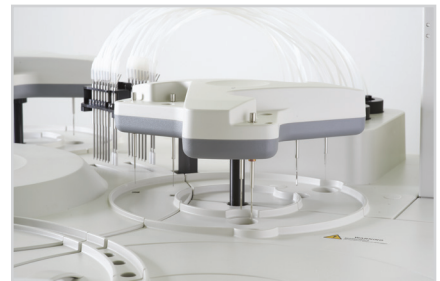


High Precision Aspirating

- 1.5 μ l-25 μ l, with increment of 0.1 μ l for sample probe
- Non-touch dispensing for sample
- 80 μ l-200 μ l, with increment of 0.5 μ l for R11 and R12 probes
- 10 μ l-200 μ l, with increment of 0.5 μ l for R21 and R22 probes

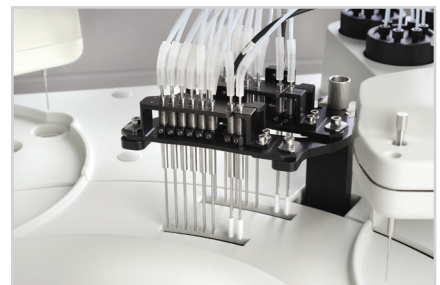
High Performance Reaction System

- Two 6-head mixing units for reagent and samples
- Direct solid heating for reaction carousel
- Glass cuvettes for permanent use



Efficient Washing System

- Interior & exterior probe washing with high pressure pre-heated water
- Programmable enhanced washing with detergent for reagent and sample probes
- 8-stage cuvette wash station, washing cuvettes with pre-heated detergent and water
- Two-step mixer washing with pre-heated detergent and water



Stable Cooling Compartment

- 2°C-8°C constant cooling compartment for reagents
- Constant cooling compartment for calibrators and controls in sample carousel



Accurate, Reliable Results

To ensure accuracy, reliability and correlation of diagnostic data, Mindray utilizes the International Standard in result reporting. To assure ease of report retrieving, Mindray establishes the Mindray Clinical Chemistry Measurement System for result traceability.



Standard reference system

- Adopt JCTLM reference system
- IFCC primary method for enzyme, ID/MS method for substrate
- NIST, IRMM reference materials

JCTLM, Joint Committee On Traceability In Laboratory Medicine

NIST, National Institute of Standards and Technology, USA

IRMM, Institute for Reference Materials and Measurements, EU

IFCC, International Federation of Clinical Chemistry and Laboratory Medicine



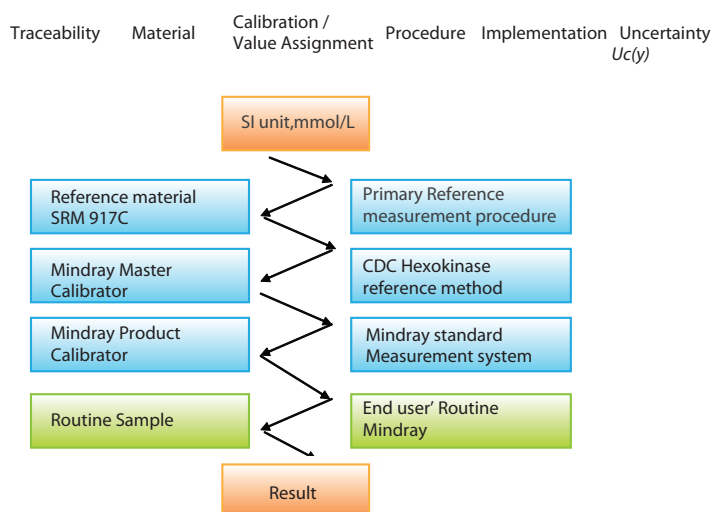
Complete traceability process

- Complete calibration hierarchy and traceability chain based on ISO standard (EN/ISO17511) from reference system to routine measurement system

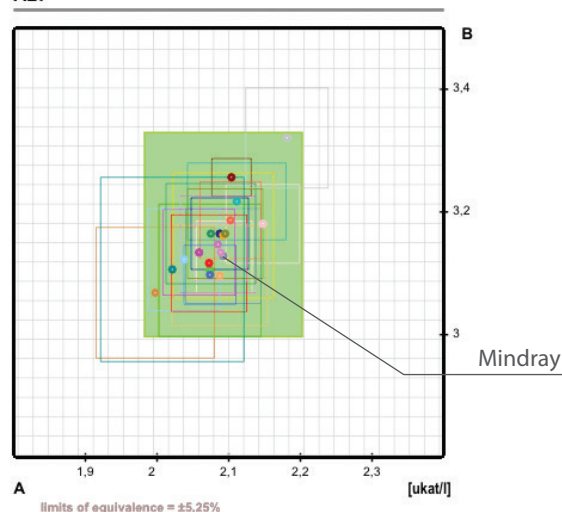
Proficiency testing for reference measurement

- Participate RELA (External quality control for reference laboratory) to verify the accuracy of the value assignment procedure.

Traceability chain of Mindray measurement system (Glu)



ALT



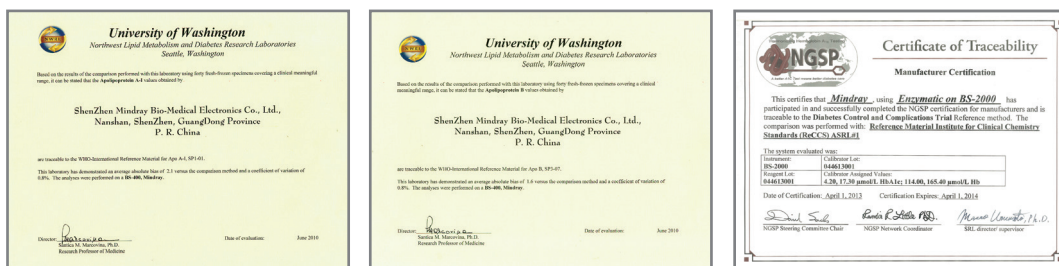
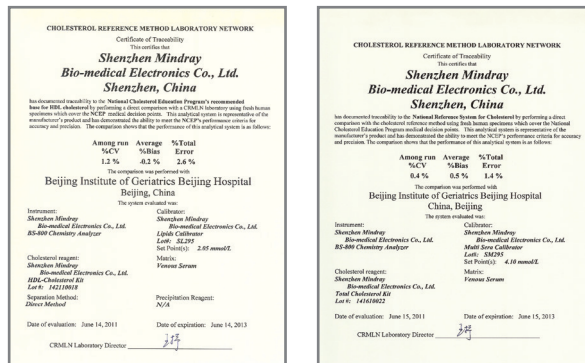
International standardization certification

- International Standardization certificates of Cholesterol and Hba1c from CRMLN and NGSP.

More information refers to website (<http://www.cdc.gov>).

CRMLN (Cholesterol Reference Method of Laboratory Network)

NGSP(National glycosylated hemoglobin standardization program)



Matched calibrators and controls

- Dedicated calibrators with traceability and specific target value
- Convenient design of multi items of calibrators and controls combined into one vial
- Long shelf life of lyophilized powder

Dedicated, high-quality reagents

- Diagnostic function test panels**

Test panels such as : Hepatic panel, renal panel, pancreatic panel, lipid panel, cardiac panel, diabetic panel, rheumatic factor panel

- Reliable analysis performance**

EP series standard (CLSI)-evaluate and optimize reagent system for reliable performance in precision, linearity, stability, specificity and anti-interference capability

- ISO standard manufacturing**

Mindray follow straightly the ISO Certified manufacturing process to ensure every lot of reagent in production are of supreme quality

Reagent Menu

Hepatic Panel

Alanine Aminotransferase (ALT)
Aspartate Aminotransferase (AST)
Alkaline Phosphatase (ALP)
 γ -GlutamylTransferase (γ -GT)
Bilirubin Direct (Bil-D) DSA Method
Bilirubin Direct (Bil-D) VOX Method
Bilirubin Total (Bil-T) DSA Method
Bilirubin Total (Bil-T) VOX Method
Total Protein (TP)
Albumin (ALB)
Total Bile Acids (TBA)
Prealbumin (PA)
Cholinesterase (CHE)
 α -L-fucosidase (AFU)
5'-nucleotidase (5'-NT)

Renal Panel

Urea (UREA)
Creatinine (CREA) Modified Jaffé Method
Creatinine (CREA)Sarcosine Oxidase Method
Uric Acid (UA)
Carbon dioxide (CO₂)
Microalbumin
 β 2-Microglobulin (β 2-MG)
Cystatin C (CysC)
Retinol binding protein(RBP)

Cardiac panel

Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Lactate Dehydrogenase (LDH)
 α -Hydroxybutyrate Dehydrogenase(α -HBDH)
High sensitive C-reactive protein(HS-CRP)
Homocysteine (HCY)
Myoglobin(MYO)
D-Dimer(D-Dimer)

Inorganic & Anemia

Iron (Fe)
Ferritin (FER)
Transferrin (TRF)
Calcium (Ca)
Magnesium (Mg)
Phosphorus (P)
Unsaturated iron binding capacity (UIBC)
Glucose-6-phosphate dehydrogenase (G6PD)

Lipid Panel

Total Cholesterol (TC)
Triglycerides (TG)
HDL-Cholesterol (HDL-C)
LDL-Cholesterol (LDL-C)
Apolipoprotein A1 (ApoA1)
Apolipoprotein B (ApoB)
Lipoprotein(a) [Lp(a)]

Immune Panel

Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Immunoglobulin E (IgE)
Complement C3 (C3)
Complement C4 (C4)

Diabetes Panel

Glucose (Glu) GOD-POD Method
Glucose (Glu) HK Method
Hemoglobin A1c (HbA1c)
Fructosamine (FUN)
 β -Hydroxybutyrate(β -HB)

Rheumatism Panel

C-reactive protein (CRP)
Rheumatoid Factor (RF)
Antistreptolysin "O"(ASO)

Pancreatitis Panel

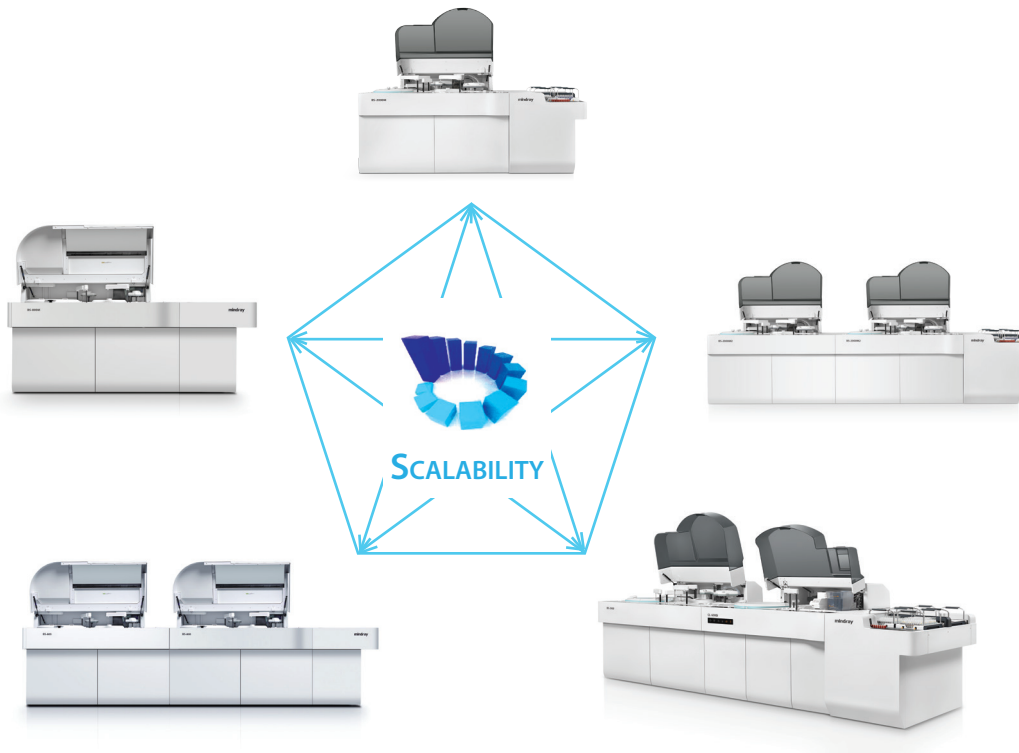
α -Amylase (α -AMY)
Lipase (LIP)

Lung Panel

Adenosine Deaminase (ADA)
Angiotensin Converting Enzyme(ACE)



Flexible Scalability



BS-2000 Modular System, the highest throughput chemistry system ever designed by Mindray, is a brand new solution package for hospitals and clinical laboratories with high sample volumes. It combines innovation and high performance into a fully integrated solution, together with the complete line of original reagents, calibrators with metrological traceability and controls. It offers customers a versatile solution with high efficiency, automation and scalability. Furthermore it will lay the foundation for further modular integration with Mindray's future products.



Technical Specifications *

System function

Fully automated, discrete, random access, STAT sample priority
Throughput: 2000 photometric tests/hour, up to 600 tests/hour for ISE
Measuring Principles: Colorimetry, Turbidimetry and Indirect ISE method
Methodology: End-point, Fix-time, Kinetic, optional ISE

Sample Handling

Sample Carousel: 140 positions, 25 cooling positions for calibrators and controls
Sample Delivery Module (SDM): Patented double-layer & basket delivery design, up to 600 sample positions

Sample Racks: 10 samples/rack
Sample Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection
Sample Volume: 1.5μl-25μL, with increment of 0.1μL
Probe Washing: Interior and exterior probe washing
Programmable enhanced washing with detergent
Carry over < 0.1%
Automatic Sample Dilution: Pre-dilution, post-dilution and auto-dilution for sample
Dilution ratio: 4~134
Barcode Reader: Integrated bar code scanner in SDM
Sample carousel barcode scanner (optional)

Reagent Handling

Reagent Carousel: 140 positions
Refrigerated compartment (2~8 °C)
Reagent Bottle: Mindray 20ml and 62ml
Barcode Reader: Bar code scanner for two reagent carousels
Reagent Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection
Reagent Volume: 80μl-200μl, with increment of 0.5μl for R11 & R12 probes
10μl-200μl, with increment of 0.5μl for R21 & R22 probes
Probe Washing: Automatic interior and exterior probe washing
Programmable enhanced washing with detergent
Carry over < 0.1%
Reagent Loading: Reagent bottles can be online loaded while instrument is running

Reaction System

Reaction Carousel: 412 permanent glass cuvettes with 8-stage automatic washing
Cuvette: Optical length 5mm
Reaction Volume: 80μl-280μl
Reaction Temperature: 37 °C with fluctuation of ± 0.1 °C
Mixing Unit: Two 6-head highly polished mixing bar units for reagent mixing and sample mixing; two-step washing with pre-heated detergent and water

Optical System

Light Source: 12V/50W Halogen-tungsten lamp
Photometer: Holographic concave flat-field gratings
Wavelength: 13 wavelengths: 340nm~850nm
Absorption Range: 0~3.5A (10mm conversion)
Resolution: 0.0001Abs

ISE Module (Optional)

Indirect Method, Na⁺, K⁺, Cl⁻ tests, with 22μl sample volume
Throughput: up to 600 tests/hour

Operation Unit

Operation System: Window XP Professional or Windows 7 Professional (32bit)

Working Conditions

Power Supply: 110V/115V~, 60Hz; 220V-240V~, 50Hz; 220V/230V~, 60Hz
Input Power: 4500VA for each analytical unit, SDM: 800VA
Operating Temperature: 15 °C~30 °C
Relative Humidity: 35%RH~85%RH, without condensation
Water consumption: <85L/hour De-ionized water
Dimension: 1600mm(Length)×1050mm(Depth)×1300mm (Height)
for each analytical units, 710mm(Length)×1020mm(Depth)
×1000mm(Height) for SDM
Weight: ≤550Kg for each analytical unit, 150kg for SDM

*For single analytical unit

BioSystems

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 thirteen (13) pages joined herewith, meet the applicable provisions of the

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

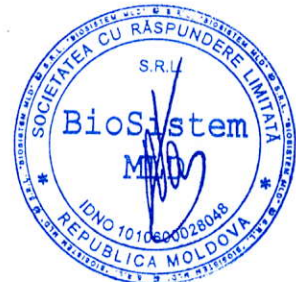
Barcelona, November 3rd, 2023

P. Vila

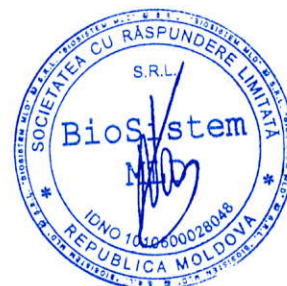
BioSystems

Costa Brava, 30. 08030 BCN
NIF: A08678823

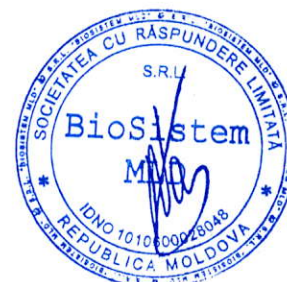
Pau Vila Cases, PhD
CEO
BioSystems S.A.



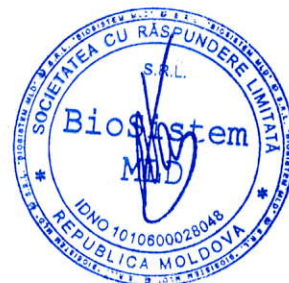
CLINICAL CHEMISTRY - BIOCHEMISTRY	
PRODUCT NAME	CODE
a-AMYLASE - DIRECT	11583
	11550
	12550
	21550
	23550
a-AMYLASE - EPS	11534
	21534
	12535
a-AMYLASE-PANCREATIC	11799
	12799
	21799
alpha-GLUCOSIDASE	12522
	21522
ACID PHOSPHATASE (ACP)	11548
ADENOSINE DEAMINASE	12754
	23754
ALANINE AMINOTRANSFERASE (ALT/GPT)	11832
	11533
	11568
	11562
	12533
	21533
	23533
ALBUMIN	11573
	11547
	12547
	21547
	23547
ALKALINE PHOSPHATASE (ALP) - AMP	11592
	11593
	11598
	12518
	21592
	23592



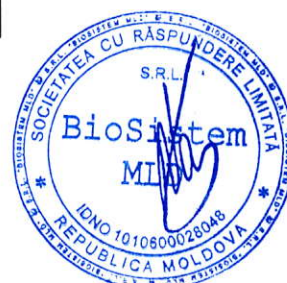
ALKALINE PHOSPHATASE (ALP) - DEA	11590 11591 11597 12514 21590 23590
ASPARTATE AMINOTRANSFERASE (AST/GOT)	11830 11531 11567 11561 12531 21531 23531
BILIRUBIN (DIRECT)	11511 11545 12504 21504 23504
BILIRUBIN (TOTAL AND DIRECT)	11515 11555
BILIRUBIN (TOTAL)	11510 11544 12506 21506 23506
CALCIUM-ARSENATO	11570 11571 12570 21570 23570
CALCIUM-CRESOLPHTHALEIN	11811 11812 12513 21511 23511
CALCIUM-MTB	11527 11507
CARBON DIOXIDE (CO2)	11558 11827 12558 21558
CHOLESTEROL	11805 11505 11506 11539 12505 21505 23505
CHOLESTEROL HDL	11523



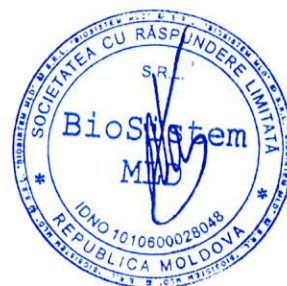
CHOLESTEROL HDL DIRECT	21557
	23557
	11757
	12757
	21594
	23594
CHOLESTEROL HDL PRECIPITATING REAGENT	11648
CHOLESTEROL LDL DIRECT	12585
	21585
	23585
	11785
	12785
	21785
	23785
CHOLESTEROL LDL PRECIPITATING REAGENT	11579
CHOLINESTERASE (CHE)	11588
	11589
	12588
	21588
CITRATE	11795
	11895
	23795
COPPER - PAESA	11837
CREATINE KINASE (CK)	11790
	11791
	12524
	21790
	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



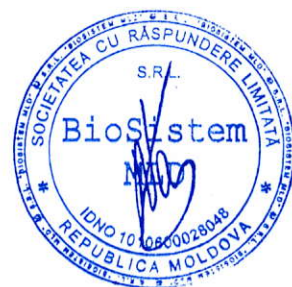
GLUCOSE	11803 11503 11504 11538 12503 21503 23503
GLUCOSE-HEXOKINASE	11656 12756 21656 23656
IRON- CHROMAZUROL	11546
IRON-FERROZINE	11509 12509 21509 23509
LACTATE	11736 12736 21736 23736
LACTATE DEHYDROGENASE (LDH)	11580 11581 12580 21580 23580
LACTATE DEHYDROGENASE (LDH) - IFCC	11586 11587 21586 23586
LIPASE	12793 23793 11760 12760 21760
MAGNESIUM	11797 12797 21797 23797
PHOSPHORUS	11508 12508 21518 23518
PROTEIN (TOTAL)	11800 11572 11500 11553 12500 21513 23513
PROTEIN (URINE)	11501 11559 12501 21512 23512



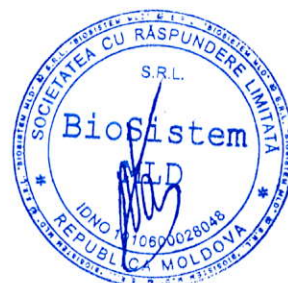
PYRIDOXAL PHOSPHATE	11666
TOTAL IRON BINDING CAPACITY (TIBC)	11554
TRIGLYCERIDES	11828
	11528
	11529
	12528
	21528
	23528
UNSATURATED IRON BINDING CAPACITY (UIBC)	11835
	12835
	21835
UREA/BUN - COLOR	11536
	11537
UREA/BUN - UV	11516
	11517
	11541
	12516
	21516
	23516
URIC ACID	11821
	11521
	11522
	11540
	12521
	21521
	23521
ZINC	12526
ADENOSINE DEAMINASE (ADA)	12754
	23754
AMMONIA	12532
	23532
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796
	21796
b-HYDROXYBUTYRATE	12525
	21525
ETHANOL	12789
	21789
HOMOCYSTEINE	12737
	21737
	23737
OXALATE	12539
	23539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551
	21551
	23551
CLINICAL CHEMISTRY- TURBIDIMETRY	
PRODUCT NAME	CODE



a1-ACID GLYCOPROTEIN	31928 23107
ALBUMIN (MICROALBUMINURIA)	31324 31924 13324 22324 23324
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	61004 61005 61009
ANTI-STREPTOLYSIN O (ASO)	31323 31923 31031 13923 22923 23923
ANTITHROMBIN III	31936 13936 22936 23936
APOLIPOPROTEIN A-I (APO A-I)	31095 23095
APOLIPOPROTEIN B (APO B)	31098 23098
b2-MICROGLOBULIN	31920 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-er (CRP-er)	22942 23942
C-REACTIVE PROTEIN-hs (CRP-hs)	31927 13927 22927 23927



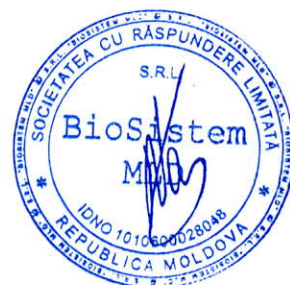
D-DIMER	21519
FERRITIN	31934
	31935
	22934
	23934
	13934
FIBRINOGEN	31600
	13600
	22804
	23804
FIBRINOGEN CLAUSS	61002
	61003
	61020
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)	31047
	13047
	22047
	22147
IMMUNOGLOBULIN A (IgA)	31071
	31077
	13082
	23101
IMMUNOGLOBULIN G (IgG)	31070
	31076
	13081
	23100
IMMUNOGLOBULIN M (IgM)	31072
	31078
	13083
	23102
PREALBUMIN	31929
	23106
PROTHROMBIN TIME (PT)	61001
RHEUMATOID FACTORS (RF)	31322
	31922
	31030
	13922
	22922
	23922
THROMBIN TIME (TT)	61000
TRANSFERRIN	31091
	31092
	31093
	13091
	22105
	23105
CLINICAL CHEMISTRY- MICROCOLUMN CHROMATOGRAPHY	
PRODUCT NAME	CODE
17-HYDROXYCORTICOSTEROIDS (17-OH)	11006
17-KETOSTEROIDS	11002



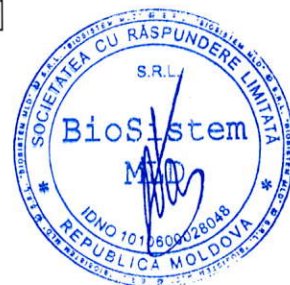
5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)	11017
5-HYDROXYINDOLEACETIC ACID (5-HIAA)	11010
HEMOGLOBIN A2	11077
METANEPHRINES	11022
VANILMANDELIC ACID	11003
CLINICAL CHEMISTRY- STANDARDS & CALIBRATORS	
PRODUCT NAME	CODE
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	31130
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
BIOCHEMISTRY CALIBRATOR (BOVINE)	18011
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
BILIRUBIN STANDARD	11513
CHOLESTEROL HDL/LDL CALIBRATOR	11693
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11824
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
D-DIMER STANDARD	18077
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11750
PROTEIN CALIBRATORS	31075
PROTEIN (URINE) STANDARD	11603
RHEUMATOID FACTORS (RF) STANDARD	31116



CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL	
PRODUCT NAME	CODE
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
D-DIMER CONTROLS	18078
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 I	18080
OXALATE CONTROL URINE II	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212
RHEUMATOID CONTROL SERUM	31213
RHEUMATOID CONTROL SERUM II	31214
AUTOIMMUNITY-IF A (IMMUNOFLUORESCENCE)	
PRODUCT NAME	CODE
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	44574
	44575
	29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148
	44548
	44715
	44557
	44710



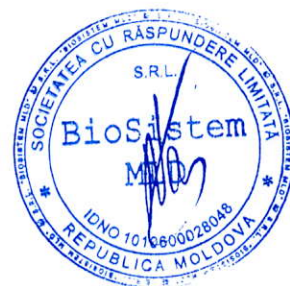
ANTI-ISLET CELL ANTIBODIES (AICA)	44609 44572
ANTI-KERATIN ANTIBODIES (AKA)	44618 44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510 44514 44511 44515
ANTI-nDNA ANTIBODIES (nDNA)	44825 44818 44817 44820 44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850 44851 44852 44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (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 (ASiMA)	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
AUTOANTIBODIES-RK/RS (AA-RK/RS)	44758 44568
AUTOANTIBODIES-RL/RK/RS (AA-RL/RK/RS)	44558 44648 44570 44639
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	44588
AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS	
PRODUCT NAME	CODE
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549 44893 44732
AICA POSITIVE CONTROL	44577



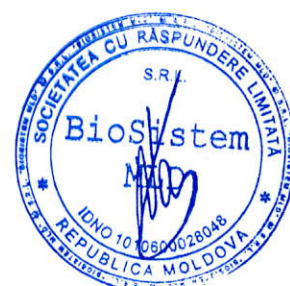
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
ANA-Ce POSITIVE CONTROL	44891
ANA-Ho POSITIVE CONTROL	44585
ANA-Nu POSITIVE CONTROL	44502
ANA-Sp POSITIVE CONTROL	44890
APCA POSITIVE CONTROL	44504
ASA-bm POSITIVE CONTROL	44503
ASA-is POSITIVE CONTROL	44532
ASMA POSITIVE CONTROL	44562
ASMA POSITIVE CONTROL	44522
ASMA POSITIVE CONTROL	44892
ASMA 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
FITC/EVANS (R)	44912
GBMA POSITIVE CONTROL	44590
GLYCIN	44836
PRODUCT NAME	CODE
IgA FITC/EVANS	44697
IgG FITC/EVANS	44834
IgG FITC/EVANS (M)	44847
LKM POSITIVE CONTROL	44882
MOUNTING MEDIUM	44766
nDNA POSITIVE CONTROL	44694
NEGATIVE CONTROL	44542
P-ANCA POSITIVE CONTROL	44894
PBS (10x)	44696
X-ANCA POSITIVE CONTROL	44889
AUTOIMMUNITY - ELISA	44855
PRODUCT NAME	CODE
ANA-SCREENING	44913
ANTI-ANNEXIN V IgG/IgM (ANX)	44592
ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)	44896
ANTI-BPI ANTIBODIES	
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	
ANTI-CATHEPSIN G ANTIBODIES	
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	



ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	44860
ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)	44885
ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)	44884
ANTI-dsDNA ANTIBODIES	44705
ANTI-ELASTASE ANTIBODIES	44907
ANTI-GBM ANTIBODIES-EIA (GBM)	44870
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	44704
ANTI-HISTONES ANTIBODIES (HIS)	44862
ANTI-INSULIN ANTIBODIES (INS)	44873
ANTI-Jo1 ANTIBODIES	44864
ANTI-LACTOFERRIN ANTIBODIES	44908
ANTI-LYSOZYME ANTIBODIES	44909
ANTI-M2 ANTIBODIES (M2)	44871
ANTI-MPO ANTIBODIES (P-ANCA)	44790
ANTI-NUCLEOSOME ANTIBODIES (NCL)	44861
ANTI-PHOSPHOLIPID IgG/IgM (APLA)	44867
ANTI-PR3 ANTIBODIES (C-ANCA)	44791
ANTI-RIBOSOMAL P ANTIBODIES (Rib P)	44866
ANTI-Sci70 ANTIBODIES	44863
ANTI-Sm ANTIBODIES	44755
ANTI-Sm/RNP ANTIBODIES	44770
ANTI-SSA (Ro) ANTIBODIES	44765
ANTI-SS-B (La) ANTIBODIES	44750
ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)	44796
ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI- TPO)	44795
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)	44754
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)	44798
ASCA-IgG/IgA (ASCA)	44872
ENA4-PROFILE	44775
ENA 6-PROFILE	44910
ENA6-SCREENING	44740
RAPID TESTS - LATEX AGGLUTINATION	
PRODUCT NAME	CODE
ANTI-STREPTOLYSIN O (ASO) - SLIDE	31019
	31319
	31086
	31448
C-REACTIVE PROTEIN (CRP) - SLIDE	31011
	31311
	31012
	31107
RHEUMATOID FACTORS (RF) - SLIDE	31013
	31313
	31014
	31108
INFECTIOUS IMMUNOLOGY- SYPHILIS	
PRODUCT NAME	CODE



RPR-CARBON	36001 36002
INFECTIOUS IMMUNOLOGY- FEBRILE ANTIGENS	
PRODUCT NAME	CODE
FEBRILE SERODIAGNOSTICS SALMONELLA	33080 33081
FEBRILE SERODIAGNOSTICS PROTEUS OX19	33311
FEBRILE SERODIAGNOSTICS PROTEUS POSITIVE CONTROL	33502
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI AH	33301
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI AO	33302
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI BH	33303
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI BO	33304
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI CH	33305
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI CO	33306
FEBRILE SERODIAGNOSTICS SALMONELLA POSITIVE CONTROL	33510
FEBRILE SERODIAGNOSTICS SALMONELLA TYPHI H	33307
FEBRILE SERODIAGNOSTICS SALMONELLA TYPHI O	33308



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DECLARATION OF CONFORMITY

To whom it may concern,

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

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

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

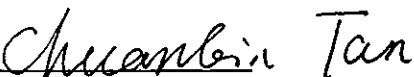
Product Category(ies): Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis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

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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
α -Amylase (α -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)	/	/
α -Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/

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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turbidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
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	/	/
Multimune Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α -L-Fucosidase Kit (CNPF method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β 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	/	/
β 2-Microglobulin (β 2-MG) Kit (Latex Immunoturbidimetric Method)	/	/
β 2-Microglobulin Control	/	/
β 2-Microglobulin Calibrator (for Serum)	/	/
β 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/

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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)	/	/
β -Hydroxybutyrate (β -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
β -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I (CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide (CLIA)	/	/
BNP Calibrators	/	/
Myoglobin (CLIA)	/	/
MYO Calibrators	/	/

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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	/	/
Adrenocorticotrophic 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	/	/

EC DECLARATION OF CONFORMITY DECLARACIÓN CE DE CONFORMIDAD

BioSystems S.A., a company established in
Costa Brava 30, 08030 Barcelona, Spain,

*BioSystems S.A., compañía establecida en
c/Costa Brava 30, 08030 Barcelona, España,*

Declares under its responsibility that the product

Declara bajo su responsabilidad que el producto

CERULOPLASMIN CALIBRATOR

Cod.: 31340

meets the applicable provisions of the **Directive 98/79/EC on in Vitro Diagnostic Medical Devices** under the specifications declared by BioSystems S.A.

cumple las disposiciones aplicables de la Directiva 98/79/CE sobre Productos Sanitarios para Diagnóstico in Vitro, bajo las especificaciones declaradas por BioSystems, S.A.

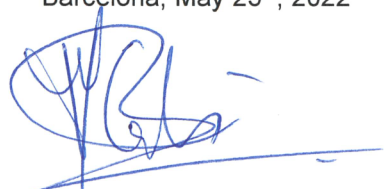
It means that the product:

Esto significa que el producto:

- 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.

- *cumple con los Requisitos Esenciales aplicables según lo establecido en el Anexo I, y su documentación técnica se realiza siguiendo los requisitos del Anexo III*
- *está clasificado como Otros Productos (todos los productos excepto los del Anexo II y para Autodiagnóstico), por ello la evaluación de la conformidad sigue el procedimiento indicado en el Anexo III de la Directiva, sin requerir la intervención de un Organismo Notificado.*

Barcelona, May 25th, 2022



Teresa Cortès
CQO



Pau Vila Cases
CEO