ORDIN DE PLATĂ

Nr. 1196 | DATA EMITERII 7 iulie 2026 | TIP.DOC.1

PLĂTIȚI: 900-00 LEI Noua sute lei 00 bani

PLĂTITOR: (R) BIOSISTEM MLD SRL

CODUL IBAN: MD95ML000000002251429243
CODUL FISCAL: 1010600028048
CODUL LEI:

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP SPITALUL RAIONAL CIMISLIA

CODUL IBAN: MD79AG000000022512564163
CODUL FISCAL: 1003605150319
CODUL LEI:

PRESTATORUL BENEFICIAR: BC'MAIB'S.A.

DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achizitie publica nr. ocds-b3wdp1-MD-1782739619425 din 09.07.2026

TIPUL TRANSFERULUI
NORMAL/URGENT/INSTANT

N

L.Ș.

CODUL TRANZACȚIEI	DATA PRIMIRII	DATA EXECUTĂRII
001		

LAZAR ANNA

LAZAR ANNA

SEMNĂTURILE EMITENTULUI

Document transmis prin instrument de plată electronic cu acces la la distanţă de tip internet-banking

/
SEMNĂTURA PRESTATORULUI

L.Ș.

MOTIVUL REFUZULUI

Nota: Responsabilitatea privind veridicitatea şi corectitudinea informaţiei indicate în ordinul de plată îi revine emitentului*

**Regulamentul cu privire la transferul de credit, debitarea directă şi atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023*

Digitally signed by Poiata Vitalie
Date: 2026.07.07 14:44:42 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

evo

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1315048**

Din От **07.07.2026 13:15**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată "BIOSISTEM MLD"

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ 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 задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **22.07.2026 13:15**

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 integrat EVO / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Интегрированный правительственный портал EVO.

Generat și semnat de Portalul guvernamental integrat EVO la **07.07.2026 13:15**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

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

Сертификат скачен с Интегрированный правительственный портал EVO (evo.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Интегрированный правительственный портал EVO (msign.gov.md)

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

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

Asociaţii:
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 şi a întreprinzătorilor individuali şi 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

Date cu caracter personal

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

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

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, 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 activităţii de întreprinzător***", cu modificarile ulterior adoptate de parlamentul RM, ***Importul, comercializarea, asistenţa tehnică si reparaţia 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.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA

_____Vitalie Poiata

L.Ş.

adresa: str. Albișoara 16/1 of.7, MD-2001 Chișinău, Republica Moldova
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Data prezentării 14.05.2026 17:01:42

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2025 - 31.12.2025

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, Societăţi cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele şi coordonatele al contabilului-şef: Dl (dna) Tel.

Numărul mediu al salariaţilor în perioada de gestiune: 12 **persoane.**

Persoanele responsabile de semnarea situaţiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANŢUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul 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	7706354	8218668
din care: 3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	6955543	7635933
3.4. mijloace de transport	084	629606	509681
3.5. inventar și mobilier	085	9423	3600
3.6. alte mijloace fixe	086	111782	69454
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	1435404	4583358
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	9141758	12802026
III. Investiţii 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: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiţii financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanţe pe termen lung şi 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 creanţe pe termen lung şi 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	9141758	12802026
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	1133	0
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	15684462	27096904
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	15685595	27096904
	II. Creanţe curente şi alte active circulante			
	1. Creanțe comerciale curente	300	4561951	4672094
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	25303	4177
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	3491833	3945862
	Total creanţe curente şi alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	8079087	8622133
	III. Investiţii 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 investiţii financiare curente (rd.380 + rd.390)	400		
	IV. Numerar şi documente băneşti	410	35607750	41827342
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	59372432	77546379

	TOTAL ACTIVE (rd.230 + rd.420)	430	68514190	90348405
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social şi 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 şi 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. Corecţii ale rezultatelor anilor precedenţi	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	560	65739792	58080217
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	26312548
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	65739792	84392765
	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	65745192	84398165
D.	**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 obligaţiuni	641		
	inclusiv: împrumuturi din emisiunea de obligaţiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	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: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	10312	4904902
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	151820	25060
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	2601490	869645
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	5376	150633
	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	2768998	5950240
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	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	68514190	90348405

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2025 pînă la 31.12.2025

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune

		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	72234217	76853747
din care: venituri din vînzarea produselor și mărfurilor	011	70297293	74037177
venituri din prestarea serviciilor și executarea lucrărilor	012	1701254	1836226
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanţare	015		
alte venituri din vînzări	016	235670	980344
Costul vînzărilor, total	020	37551083	38546632
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	37420276	38346562
costul serviciilor prestate și lucrărilor executate terților	022	130807	200070
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanţare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	34683134	38307115
Alte venituri din activitatea operațională	040	1999137	0
Cheltuieli de distribuire	050		6125
Cheltuieli administrative	060	6021871	7509530
Alte cheltuieli din activitatea operațională	070	692169	873285
Rezultatul din activitatea operaţională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	29968231	29918175
Venituri financiare, total	090	970167	1177849
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093	255488	472664
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	714679	705185

Cheltuieli financiare, total	100	2592418	1176288
din care: cheltuieli privind dobînzile	101		
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	2592418	1176288
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-1622251	1561
Venituri cu active imobilizate și excepționale	120	836616	0
Cheltuieli cu active imobilizate și excepționale	130	409025	0
Rezultatul din operaţiuni cu active imobilizate şi excepţionale: profit (pierdere) (rd.120 - rd.130)	140	427591	0
Rezultatul din alte activităţi: profit (pierdere) (rd.110 + rd.140)	150	-1194660	1561
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	28773571	29919736
Cheltuieli privind impozitul pe venit	170	3487050	3607188
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	25286521	26312548

SITUAŢIA 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 sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social şi 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 şi 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				

SITUAŢIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

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

Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiţii (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 sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Biosistem.PDF

Recipisa

Respondent
Codul fiscal: 1010600028048, denumire: "BIOSISTEM MLD" S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2025
Data prezentarii: 14.05.2026
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 14.05.2026 17:01:42

Recipisa 2

Respondent
Codul fiscal: 1010600028048, denumire: "BIOSISTEM MLD" S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2025
Data prezentarii: 14.05.2026
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 15.05.2026 13:12:02

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.

Declaration of Conformity CE

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

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

Product: **Auto Hematology Analyzer**
Model: **BC-3600**
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

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

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2011-01-14
Place, Date of Issue: Shenzhen, 2011-01-14

Signature: .....
Name of Authorized Signatory: Mr. Yang Long
Position Held in Company: Management Representative

Declaration of Conformity V 1.0

Declaration of Conformity CE

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

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

Product: **Auto Hematology Analyzer**

Model: **BC-5000**
Including reagents as following:
M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

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

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26
Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

BC-3600

Auto Hematology Analyzer

Pleasant Experience in Hematology Testing

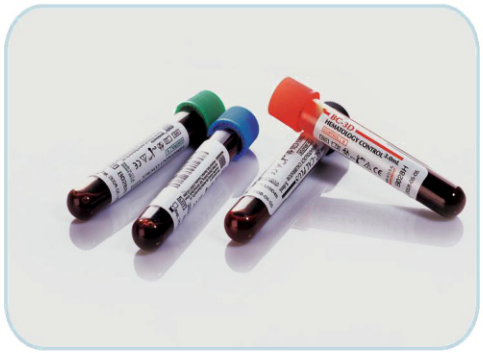
mindray
healthcare within reach

Surpassing Performance

Surpassing Performance

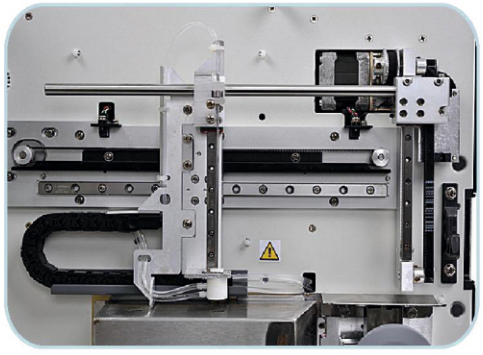
Superior Reagents, Quality Controls and Calibrators

High quality original reagents, calibrators and controls offer a complete system for our users. Cyanide free reagents allow laboratories to meet necessary environmental regulations. Complete traceability system ensures closest consistency with standard methods.



High Quality Design

New internal structural design separates electronic components from the fluidic system, decreasing interference while at the same time allowing for easier maintenance.



BC-3600

Auto Hematology Analyzer

Technical Specifications

Parameters

WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV and histograms for WBC, RBC, PLT

Principles

Electrical impedance method for cell counting and Cyanide - free for hemoglobin

Performance

Parameter	Linearity Range	Precision (CV%)
WBC (10^3/μL)	0.3 - 99.9	3.0(≥4.0)
RBC (10^6/μL)	0.2 - 7.99	2.5
HGB (g/dL)	1.0 - 24.99	2.0
MCV (fL)		2.0
PLT (10^3/μL)	10 -999	6(≥150)

Sample Volume

Prediluted	20μL
Whole Blood	21μL

Throughput

60 samples per hour

Display

Large color touch screen
Resolution: 800×600

Carryover

WBC，RBC，HGB≤0.5%
PLT≤1.0%

Connectivity

4 USB ports (for external printer, software upgrade, barcode reader, keyboard and mouse), LAN port (1), RS232 (1)

Printout

Thermal recorder, 50mm width paper, various printout formats, external printer (optional)

Operating Environment

Temperature: 15°C~30°C
Humidity: 30%~85%

Power requirement

AC 100-240V, 50/60±1Hz

Dimensions

16 in(W) x 18 in(H) x 18 in(D)

Configuration

Close Tube Sampling

Weight

62 lbs

Mindray North America
800 MacArthur Blvd., Mahwah, NJ 07430-0619,USA
Toll Free: +1(800) 288 2121
E-mail: intl-market@mindray.com www.mindray.com

Mindray is listed on the NYSE under the symbol"MR"

P/N: ENG-BC3600FDA-21285x6-20150924

mindray

BC-3600

Auto Hematology Analyzer

Labs today are facing a multitude of challenges including limited laboratory budgets, increasing requirements for high quality as well as reliable products, a shortage of experienced clinicians and so on. We understand the specific needs of end users, and use them as the foundation for our new solution BC-3600. Complete with an intuitive operation system, convenient data communication interface, excellent performance, BC-3600 is a system solution for satellite labs and clinics.

- CBC+3-DIFF, 16 parameters+3 histograms
- Throughput: 60 samples per hour
- Intuitive operation system with TFT touch screen
- Enhanced performance by proven technologies
- Closed Tube Sampling
- 40,000 results storage with histograms
- High quality QC, calibrators and reagents

User-friendly

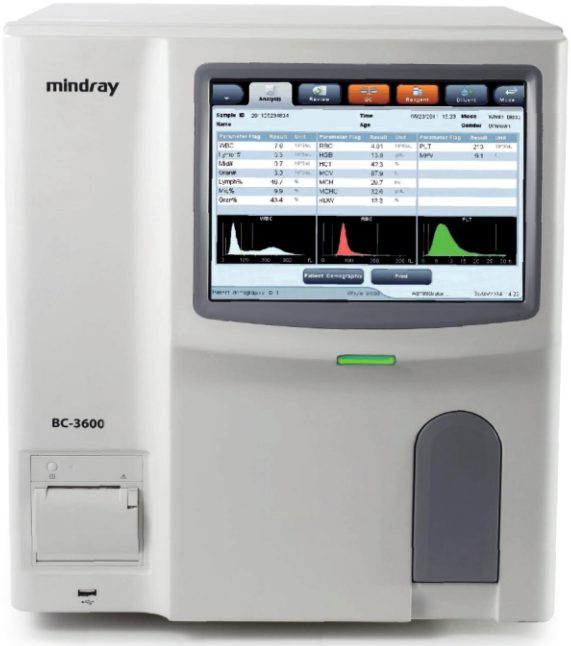
User-friendly

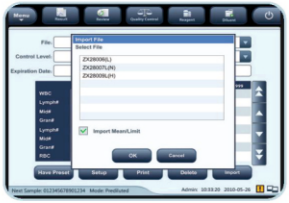
Intuitive and Powerful Software

The well organized software interface eases your operation and gives you easy control of sample results, patient records, and report customizations. Shortcut menu simplifies your work process and improves efficiency. Distinguishable areas display WBC, RBC and PLT results clearly. Automatic maintenance programs can be executed by double-clicking the function keys while operational errors can be removed with single clicks.

Complete Data Communication

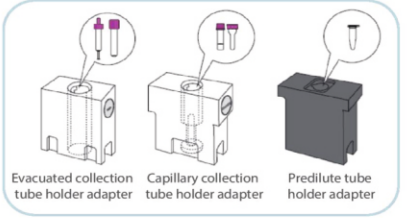
Integrated HL7 communication protocol for LIS connection. A wide selection of interface options are available including RS232 for computer connection, USB for QC assay values upload, barcode scanner, and key board connection.





Intelligence and Efficiency

Efficient ZAP and flush method removes clog completely. For Closed Tube model, 3 types of tube adaptors are provided to satisfy individual laboratory needs. With the on-line reminder function, users can conveniently monitor the reagent residual volumes through the software.



mindray

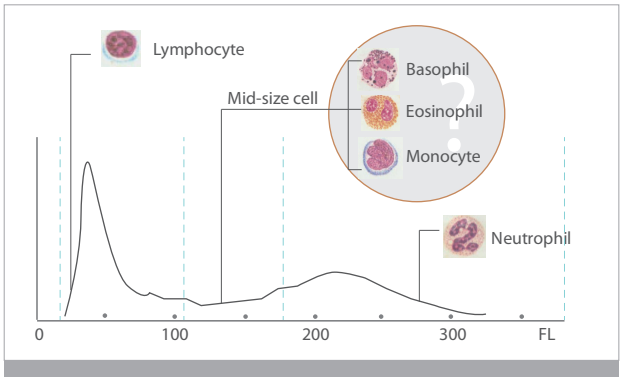
BC-5150

Auto Hematology Analyzer

A “CUTE” 5-part

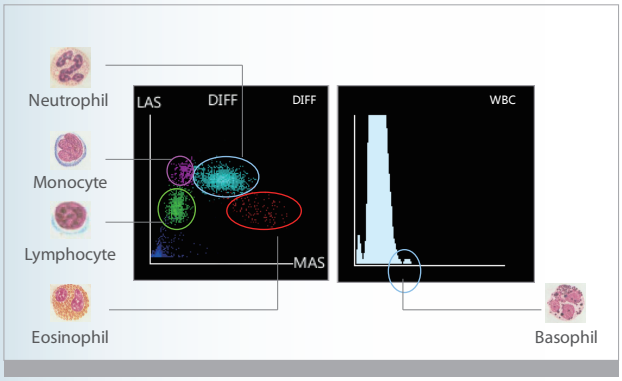
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



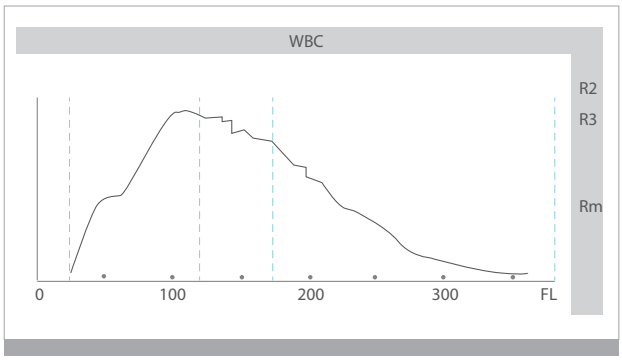
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

WBC differential: 5-part



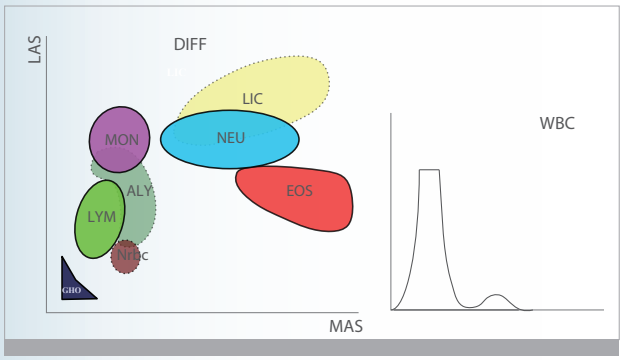
5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

Flag information: 3-part



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

Flag information: 5-part



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

Dr Marisela Ramos, lab manager

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

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

BC-5150

Auto Hematology Analyzer

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

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

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

Whole blood mode, Capillary whole blood mode and Prediluted mode

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

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

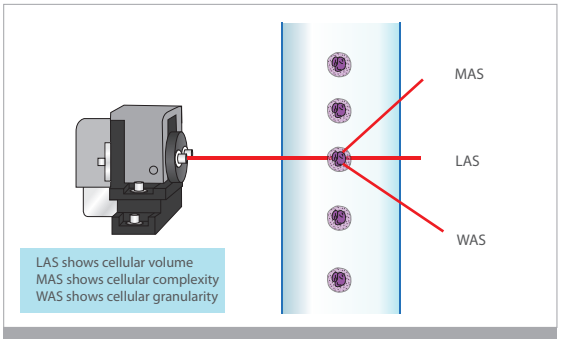
10.4 inch large TFT touch screen with user-friendly software

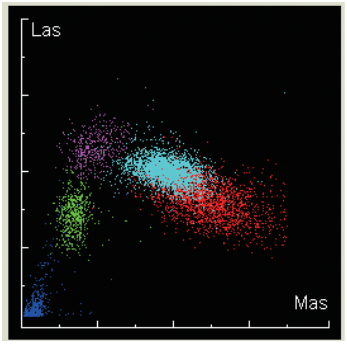
Large storage capacity: up to 250,000 samples

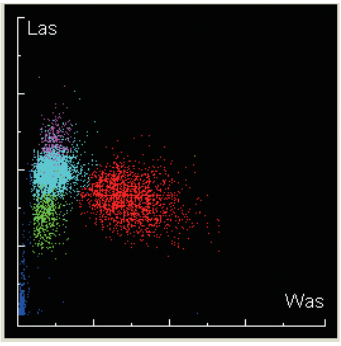
Throughput: 60 samples per hour

Sample volume is only 15μL 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.

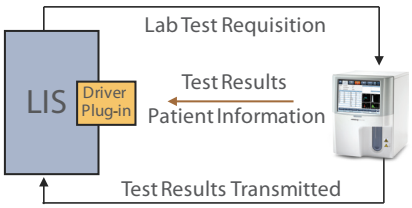
Utility

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 it's convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.

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

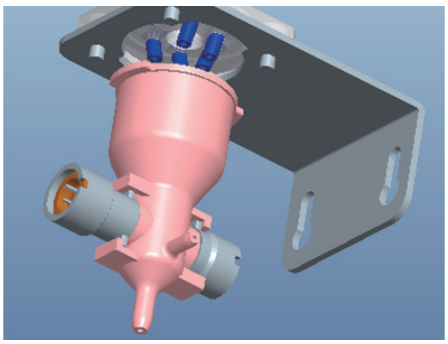
4 USB ports are located on the instrument's left side. They permit BC-5150 users to transmit data conveniently and connect with printers, keyboard, mouse, barcode scanner, etc.



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

Technology

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



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

Efficient

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

Technical Specifications

Principles
Impedance method for RBC and PLT counting
Cyanide free reagent for hemoglobin test
Flow Cytometry (FCM) + Tri-angle laser scatter + Chemical dye method for WBC 5-part differential analysis and WBC counting

Parameters
25 parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.
24 research parameters including LIC%, LIC#, ALY%, ALY#,PLT Clump#, PLT Clump%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%, PDW-SD,NLR,PLR, Neu-X, Neu-Y, Neu-Z, Lym-X, Lym-Y, Lym-Z, Mon-X, Mon-Y, Mon-Z
3 histograms for WBC, RBC and PLT
4 scattergrams for WBC differential

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

Performance

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

Sample Volume

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

Throughput
60 samples per hour

Display
10.4 inch TFT Touch Screen

Multi-language
Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity
Up to 250,000 results including numeric and graphical information

Communication
LAN port supports HL7 protocol

Interface
USB, LAN
Support bi-directional LIS

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

Operating Environment
Temperature: 10°C~30°C
Humidity: 20%~85%
Air pressure : 70 kPa~106 kPa

Power requirement
100V-240V
50Hz/60Hz

Dimension and Weight
Depth(400 mm) x width(320 mm) x height(410 mm)
Weight :24kg

www.mindray.com

P/N: ENG-BC-5150-210285x6P-20190806

mindray
healthcare within reach

Declaration of Conformity V 4.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-3600** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **M-30R RINSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking:	2011-01-14
Place, Date of Issue:	Shenzhen, 2012.12.7
Signature:	.....
Name of Authorized Signatory:	Mr. Tan ChuanBin
Position Held in Company:	Manager ,Technical Regulation

Declaration of Conformity V 4.0

Declaration of Conformity CE

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

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

Product: **Auto Hematology Analyzer**

Model: **BC-3300**
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

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

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2011-01-14

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: .....

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity CE

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

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

Product: **Auto Hematology Analyzer**
Model: **BC-3300CT**
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

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

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2011-01-14

Place, Date of Issue: Shenzhen, 2012.12.7

Signature: .....

Name of Authorized Signatory: Mr. Tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 4.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**ULTIMA 3** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **M-30R RINSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking:	2011-08-19
Place, Date of Issue:	Shenzhen, 2012.12.7
Signature:	.....
Name of Authorized Signatory:	Mr. Tan ChuanBin
Position Held in Company:	Manager ,Technical Regulation

Declaration of Conformity V 4.0

Applied Standards List

Product:

Auto Hematology Analyzer
BC-3600 、BC-3300、 BC-3300CT、ULTIMA 3
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic reagents
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
EN ISO 14971:2007	Medical devices - Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipmentfor measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010:2005	Safety requirements for electrical equipment for measurement,

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	control and laboratory use - Part 2-010:Particular requirements for laboratory equipment for heating of materials
EN 61010-2-081:2002 ++A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61326-1;2006	Electrical equipment for measurement control and laboratory use-EMC requirements-Part1: General requirement
EN 61326-2-6:2006	Electrical equipment for measurement control and laboratory use-EMC requirements-Part2-6: Particular requirement-In vitro diagnostic (IVD) medical equipment
EN 62366:2008	Medical devices —Application of usability engineering to medical devices
EN 62304 :2008	Medical device software- Software life cycle processes
ISO13485:2003/AC:2009	Medical devices - Quality management systems - Requirements for regulatory purposes

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices