

ORDIN DE PLATA NR.: 2050

TIP.DOC. 1

DATA EMITERII: 27 aprilie 2023

PLATITI: 14000-00

LEI: Patrusprezece Mii lei 00 bani

PLATITOR: (R) 'BIOSISTEM
MLD" SRL

CONTUL DE PLATI/CODUL IBAN

MD95ML000000002251429243

CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR

CODUL BANCII:

BC"Moldindconbank"S.A. fil."Invest" Chisinau

:MOLDMD2X329:

BENEFICIAR (R) IMSP AMT Bo
tanica

CONTUL DE PLATI/CODUL IBAN

MD63VI0000002251030103MDL

CODUL FISCAL :1003600153360 /

PRESTATORUL BENEFICIAR

CODUL BANCII:

B.C."VICTORIABANK"S.A.

:VICBMD2X

DESTINATIA PLATII: Pentru garantia pentru:
oferta la procedura de achizitie public:
a nr. ocds-b3wdp1-MD-1679558248982 din 2:
8.04.2023

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI: 001:

DATA PRIMIRII: 27/04/2023

DATA EXECUTARII:

SEMNAURILE

EMITENTULUI

CONDUCATOR: Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:

DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:

SIB3DQEBcUAMCixIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQm1

(semnatura electronica)

CONTABIL-SEF: Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:

DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:

SIB3DQEBcUAMCixIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:

DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:

YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQm1lv

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNAURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.



GUVERNUL
REPUBLICII MOLDOVA



SERVICIUL FISCAL DE STAT



Portalul
Guvernamental
pentru afaceri

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Din
От

1

DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare

Фискальный код/Идентификационный номер

Denumirea

Наименование

2

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

La data emiterii prezentului certificat restanța față de bugetul public național constituie/На дату выдачи данной справки, недоимка перед национальным публичным бюджетом составляет

lei/лей

3

VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО



Prezentul certificat este eliberat în temeiul Art. 131, alin. (5³) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5³) Налогового кодекса №1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

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 de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași 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 la adresa: <https://msign.gov.md>.

Сертификат выгружен с Правительственного Портала Предпринимателя (<https://mcabinet.gov.md>) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы, выдаваемые на бумаге органами налоговой администрации.
Проверку подлинности электронной подписи можно осуществить по адресу: <https://msign.gov.md>.

SITUAȚIILE FINANCIARE
pentru perioada 01.01.2022 - 31.12.2022

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DDF RISCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: SECTORUL RISCANI STR.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: 5 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:	021		
	2.1. concesiuni, licențe și mărci			
	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	3559998	3384131
	din care:	081		
	3.1. clădiri			
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	3533108	3363063
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085	26890	21068
	3.6. alte mijloace fixe	086		
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120	1162136	5250844
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	4722134	8634975
	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:			
	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 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	4722134	8634975
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	5346	13899
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	9147976	11123640
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	9153322	11137539
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2182471	4552459
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	208171	27696
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	1608597	2268111
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	3999239	6848266
	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	9861933	10281443
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	23014494	28267248
	TOTAL ACTIVE (rd.230 + rd.420)	430	27736628	36902223
	P A S I V			
C.	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	26634334	22485398
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	13391573
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	26634334	35876971
	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	26639734	35882371
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:	641		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	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	343711	5266
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	355528	143160
	6. Datorii față de personal	760	350	866
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	150263	831429
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	247042	39131
	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	1096894	1019852
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	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	27736628	36902223

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2022 până la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	38680547	40621876
din care:			
venituri din vânzarea produselor și mărfurilor	011	37724557	39203671
venituri din prestarea serviciilor și executarea lucrărilor	012	951393	1390733
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	4597	27472
Costul vânzărilor, total	020	24434231	22086174
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	24433364	21991682
costul serviciilor prestate și lucrărilor executate terților	022		92356
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026	867	2136
Profit brut (pierdere brută) (rd.010 - rd.020)	030	14246316	18535702
Alte venituri din activitatea operațională	040	5189	128694
Cheltuieli de distribuire	050	6076	15271
Cheltuieli administrative	060	1788732	3076978
Alte cheltuieli din activitatea operațională	070	1870642	1325483
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10586055	14246664

Venituri financiare, total	090	1517765	1530710
din care:	091		
venituri din interese de participare			
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	30619	250190
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	1487146	1280520
Cheltuieli financiare, total	100	249562	512939
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	249562	512939
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1268203	1017771
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	1268203	1017771
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	11854258	15264435
Cheltuieli privind impozitul pe venit	170	1450263	1872862
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	10403995	13391573

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				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	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 pînă 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		
Dobînzî 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		
Dobînzî 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 sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2022

Дата предоставления: 28.03.2023

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 28.03.2023 14:26:11

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Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2022

Дата предоставления: 28.03.2023

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 28.03.2023 14:55:24

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.



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

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

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

A. Sizy
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

Cert.Code: YFPX2022061000004

CERTIFICATE

Award to

Nasedchin Alexander

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Hematology

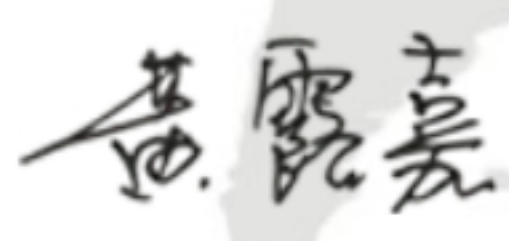
Low-High 5-DIFF Series: BC-700 Series

Level: Service Professional

2022-06-10

China

Nina Huang
Manager



Training Department
Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

2022.06.10

Date:
(Valid for two years)

Declaration of Conformity



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: Hematology Control

Model: BC-6D

Applied Hematology BC-6800、BC-6600、BC-6000、BC-6100、
BC-6000Plus、BC-6100Plus、BC-6200、BC-6800Plus
BC-6700Plus、BC-6600Plus

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: 2012-03-29

Place, Date of Issue: Shenzhen, 2017-12-18

Signature:

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

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 ISO15223-1:2012	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 23640: 2011	Evaluation of stability of in vitro diagnostic reagents
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices
ISO 14971:2012	Medical devices - Application of risk management to medical devices

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: DS DILUENT

Catalogue Number: /

Basic UDI-DI: 69449040XQSI-004DM-6S**X8

Intended Purpose: The DS DILUENT participates in the measurement of parameters related to RBC, PLT, WBC, RET and NRBC.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: DS DILUENT

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN-ISO-14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: ESR Solution Reagent

Catalogue Number: 105-026688-00、105-026689-00

Basic UDI-DI: 69449040 XQSI-CLEANSER**T3

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking:

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022.2.25

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: ESR Solution Reagent

Catalogue Number: 1105-026688-00、105-026689-00

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: ESR Solution Reagent

Catalogue Number: 105-026688-00、105-026689-00

Basic UDI-DI: 69449040 XQSJ-CLEANSER**T3

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

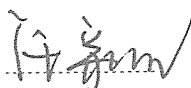
Identification of the Certificate: /

Start of CE-Marking: 2022.3.8 2022.3.8

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022.3.8

Signature:

 2022.3.8

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation

Applied Standards List

Product: ESR Solution Reagent

Catalogue Number: 1105-026688-00、105-026689-00

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6DR DILUENT

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-6DR DILUENT participates in the measurement of RET-related parameters together with M-6FR DYE / M-68FR DYE.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6DR DILUENT

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6FD DYE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-6FD DYE participates in WBC differentiation in the DIFF channel together with M-6LD LYSE.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6FD DYE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6FN DYE

Catalogue Number: /

Basic UDI-DI: 69449040XQSI-004DM-6S**X8

Intended Purpose: The M-6FN DYE participates in the measurement of Baso-related and NRBC-related parameters together with M-6LN LYSE.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6FN DYE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6FR DYE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-6FR DYE participates in the measurement of RET-related parameters together with M-6DR DILUENT

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6FR DYE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-68LB LYSE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-68LB LYSE participates in WBC counting and measurement of
basophil-related parameters

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-68LB LYSE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6LD LYSE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-6LD LYSE participates in WBC differentiation in the DIFF channel together with M-6FD DYE / M-68FD DYE

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6LD LYSE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6LH LYSE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: The M-6LH LYSE formulated to measure the hemoglobin-related parameters.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature:

Name of Authorized Signatory:

Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6LH LYSE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: M-6LN LYSE

Catalogue Number: /

Basic UDI-DI: 69449040XQSJ-004DM-6S**X8

Intended Purpose: This product participates in the measurement of Baso-related and NRBC-related parameters together with M-6FN DYE / M-68FN DYE.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

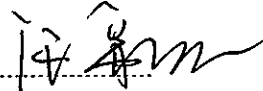
Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022-4-19

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022-4-19

Signature: 

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation Department

Applied Standards List

Product: M-6LN LYSE

Catalogue Number: /

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity



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: Hematology Calibrator

Model: SC-CAL PLUS

Applied Hematology BC-5500, BC-5200, BC-3200, BC-3000CT,

Analyzer Model: BC-3000 Plus, BC-2800, BC-2600, BC-2900
BC-1800, BC-2300, BC-2100, BC-5300, BC-5100
BC-5380, BC-5180, BC-5800, BC-5600, BC-6800, BC-6600
BC-3600, BC-3300, BC-5000, BC-5150, BC-5120, BC-5130
BC-5140, BC-5390, BC-30s, BC-31s, BC-20s, BC-21s, BC-30
BC-31, BC-6000, BC-6100, BC-6000Plus, BC-6100Plus
BC-6200, BC-6800Plus, BC-6700Plus, BC-6600Plus, BC-30e

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 under our sole responsibility 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: 2009-06-05

Place, Date of Issue: Shenzhen, 2018-8-15

Signature:

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

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 ISO15223-1:2012	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
ISO14971: 2012	Medical devices – Application of risk management to medical devices
ISO 17511: 2003	In vitro diagnostic medical device – Measurement of quantities in biological sample – Metrological traceability of values assigned to calibrator and control materials
ISO15194: 2009	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation