ORDIN DE PLATĂ

Nr. 791 | DATA EMITERII 12 februarie 2026 | TIP.DOC.1

PLĂTIȚI: 2 300-00 LEI **Doua mii trei sute lei 00 bani**

PLĂTITOR: **(R) BIOSISTEM MLD SRL**

CODUL IBAN: **MD95ML0000000022514292 43**

CODUL FISCAL: **1010600028048**

PRESTATORUL PLĂTITOR: **BC'Moldindconbank'S.A.**

BENEFICIAR: **(R) I.M.S.P. ASOCIATIA MEDICALA TERITORIALA RISCANI**

CODUL IBAN: **MD09AG000000022516083322**

CODUL FISCAL: **1003600153212**

PRESTATORUL BENEFICIAR: **BC'MAIB'S.A.**

DESTINAȚIA PLĂȚII: **Pentru garantia pentru oferta la procedura de achizitie publica nr. ocds-b3wdp1-MD-1770381202179 din 13.02.2026**

TIPUL TRANSFERULUI NORMAL/URGENT

N

L.Ș.

CODUL TRANZACȚIEI: 001

DATA PRIMIRII:

DATA EXECUTĂRII:

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: 2026.02.12 15:57:51 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Data prezentării 01.04.2025 16:19:29

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

SITUAŢIILE FINANCIARE

pentru perioada 01.01.2024 - 31.12.2024

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

Sediul:
MD:
Raionul(municipiul): 106, DDF RASCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

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

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

Persoanele responsabile de semnarea situațiilor 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	4438372	7706354
din care: 3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	4423127	6955543
3.4. mijloace de transport	084		629606
3.5. inventar și mobilier	085	15245	9423
3.6. alte mijloace fixe	086		111782
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	2337159	1435404
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	6775531	9141758
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care: 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	6775531	9141758
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	24776	1133
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11490033	15684462
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11514809	15685595
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2646694	4561951
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	45618	25303
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2251145	3491833
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	4943457	8079087
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	27361722	35607750
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	43819988	59372432

	TOTAL ACTIVE (rd.230 + rd.420)	430	50595519	68514190
	P A S I V			
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	48431994	40453271
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	25286521
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	48431994	65739792
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	48437394	65745192
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 obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	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	59765	10312
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	273711	151820
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	1766706	2601490
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	57943	5376
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2158125	2768998
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/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	50595519	68514190

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2024 pînă la 31.12.2024

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune

		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	58891757	72234217
din care: venituri din vînzarea produselor și mărfurilor	011	57105542	70297293
venituri din prestarea serviciilor și executarea lucrărilor	012	1771148	1701254
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanţare	015		
alte venituri din vînzări	016	15067	235670
Costul vînzărilor, total	020	32917436	37551083
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	32793096	37420276
costul serviciilor prestate și lucrărilor executate terților	022	124340	130807
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanţare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	25974321	34683134
Alte venituri din activitatea operațională	040	829270	1999137
Cheltuieli de distribuire	050	4167	
Cheltuieli administrative	060	3996115	6021871
Alte cheltuieli din activitatea operațională	070	879808	692169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	21923501	29968231
Venituri financiare, total	090	1070406	970167
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093	337916	255488
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	732490	714679

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

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 sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010				
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

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

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 operațională			
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 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 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 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 sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

BIOSISTEM.PDF

Объяснительная записка

SRL "Biosistem MLD"

Информация о соответствии финансовых отчетов национальным стандартам бухгалтерского учета

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

Раскрытие учетных политик

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

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

Анализ доходов от продаж

ТАБЛИЦА АНАЛИЗА РЕНТАБЕЛЬНОСТИ АКТИВОВ. ПОКАЗАТЕЛИ

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

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

Анализ финансовых результатов и рентабельности

ТАБЛИЦА АНАЛИЗА ЭКОНОМИЧЕСКОЙ РЕНТАБЕЛЬНОСТИПОКАЗАТЕЛИ

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

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

Директор SRL "Biosistem MLD" Poiata Vitalii.

Recipisa

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2024
Data prezentarii: 01.04.2025
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 01.04.2025 16:19:29

Recipisa 2

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2024
Data prezentarii: 01.04.2025
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 02.04.2025 16:10:17

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

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

EC DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product Family Name	Product Name	Registration Number
Urinalysis Reagent Strips	GLUCOSE Reagent Strips for Urinalysis	NL-CA002-2015-37666
	KETONE Reagent Strips for Urinalysis	NL-CA002-2015-37667
	PROTEIN Reagent Strips for Urinalysis	NL-CA002-2015-37665
	2 ITEMS Reagent Strips for Urinalysis(creatinine, microalbumin)	NL-CA002-2015-37670
	2 ITEMS Reagent Strips for Urinalysis (glucose, protein)	NL-CA002-2015-37669
	2 ITEMS Reagent Strips for Urinalysis (glucose, ketone)	NL-CA002-2015-37668
	3 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH)	NL-CA002-2015-37671
	3 ITEMS Reagent Strips for Urinalysis (glucose, protein, ketone)	NL-CA002-2015-37672
	4 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH, blood)	NL-CA002-2015-37674
	4 ITEMS Reagent Strips for Urinalysis (glucose, protein, pH, Specific Gravity)	NL-CA002-2015-37673
	5 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37675
	8 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37676
	9 ITEMS Reagent Strips for Urinalysis	NL-CA002-2015-37677
	A10	NL-CA002-2015-37678
	E10	NL-CA002-2015-37683
	M10	NL-CA002-2015-37684
	H8	NL-CA002-2015-37679
	H10	NL-CA002-2015-37680
	H10-800	NL-CA002-2015-37682
	H10-800(for FUS-2000)	NL-CA002-2015-37681
	H11	NL-CA002-2015-37685
	H11-MA	NL-CA002-2012-37686
	H11-MA(N)	NL-CA002-2015-37687
	H11-800	NL-CA002-2015-37688
	H11-800(for FUS-2000)	NL-CA002-2015-37689
	H11-800MA	NL-CA002-2015-37690
	H11-800MA(for FUS-2000)	NL-CA002-2015-37691
	H12-800MA	NL-CA002-2015-37692
	H12-800MA(for FUS-2000)	NL-CA002-2015-37693

	~~H13-Cr(H-800)~~	~~NL-CA002-2015-37642~~
	H13-Cr(for FUS-2000)	NL-CA002-2015-37643
	H13-Cr	NL-CA002-2015-37694
Urinalysis Reagent Strips	H14-Ca(H-800)	NL-CA002-2015-37639
	H14-Ca(FUS-2000)	NL-CA002-2015-37640
	H14-Ca	NL-CA002-2015-37641
	H13-800Cr	NL-CA002-2019-47103
	H14-800Ca	
	H13-800Cr(FUS-2000)	
	H14-800Ca(FUS-2000)	
Urinalysis Strips for Automatic Urine Analyzer	H2-Cr	NL-CA002-2019-47103
	H12-Cr	
	H12-Ca	
	H13-Ca	
	H12-MA	
FUS series Urinalysis Strips	FUS-10	NL-CA002-2015-37638
	FUS-11	NL-CA002-2015-37637
	FUS-11MA	NL-CA002-2015-37636
	FUS-12MA	NL-CA002-2012-25725
	FUS-13Cr	NL-CA002-2015-37635
	FUS-14Ca	NL-CA002-2015-37634
FUS-II series Urinalysis Strips	FUS-10 II	NL-CA002-2018-45402
	FUS-11 II	
	FUS-11MA II	
	FUS-12MA II	
	FUS-13Cr II	
	FUS-14Ca II	
Strips for Urine Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System	FUS-III Urinalysis Strips	NL-CA002-2020-54446

MANUFACTURER

Name of Company	Address	Representative
DIRUI INDUSTRIAL CO., LTD.	95 Yunhe Street New & High Tech. Development Zone Changchun, Jilin 130012 P.R. China	He Haohui

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/E-mail
Emergo Europe B.V.	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands	Tel: +31.70.345.8570 EmergoEurope@ul.com

DIRUI INDUSTRIAL CO., LTD.

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive

DIRUI INDUSTRIAL CO., LTD. hereby declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for in vitro diagnostic medical devices and Directive 98/79/EC as transposed in the national laws of the Member States. The above products meet the extension requirements of Regulation EU 2017/746.

Company Representative: He Haohui

Title: Deputy General Manager Signature: He Haohui

Date: March 3, 2023

DIRUI INDUSTRIAL CO., LTD. 迪瑞医疗科技股份有限公司

Digitally signed by Triboi Cătălina
Date: 2025.12.04 12:53:08 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

DIRUI INDUSTRIAL CO.,LTD.
95, Yunhe Street, New & High Tech. Development Zone,
Changchun, Jilin 130012,P.R. China
Tel : +86 (431) 85100409
Fax: +86 (431) 85172581
E-mail: dirui@dirui.com.cn
Http://www.dirui.com.cn

Authorization letter

To: Biosistem-mld SRL

Date: 29-07-2015

This is to certify that we, **DIRUI INDUSTRIAL CO., LTD** - China having registered offices at the below given address as a reputable manufacturer of Urine Reagent Strips, Urine Analyzers, Hematology analyzer and Chemistry Analyzer under ISO and CE condition to the international quality standards.

DIRUI INDUSTRIAL CO., LTD
95, Yunhe Street, New & High Tech Development Zone
Changchun 130012, China
Tel:0086-431-85100409
Fax:0086-431-85173354

Herein, we authorize,

Biosistem-mld SRL

as our **distributor** of Urine analyzers and consumables for their operation in Moldova. They are authorized to sell and service the products as well as to attend the local tenders with our products on Moldova market.

The commitment to supply our products to Biosistem-mld SRL will be valid until completion of the awarded contract.

For an on behalf of Dirui Industrial Co., LTD

Dima Ji
Sales Director
DIRUI INDUSTRIAL CO.,LTD

2015.07.29

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

Declaration of Conformity V1.0

Declaration of Conformity

CE

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:	69449040XQSJ-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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. BioSistem IDNO 1016600028048 REPUBLICA MOLDOVA

Declaration of Conformity V1.0

Declaration of Conformity

CE

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

SOCIETATEA CU RASPUNDERE LIMITATA
BioSystem
IDNO 1010600028006
REPUBLICA MOLDOVA

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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 V1.0

Declaration of Conformity

CE

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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
IDNO 1010600028048
REPUBLICA MOLDOVA

Declaration of Conformity V1.0

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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
BioSystem
MLD
IDNO 1010600028046
REPUBLICA MOLDOVA

Declaration of Conformity V1.0

Declaration of Conformity

CE

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:	69449040XQSJ-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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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 V1.0

Declaration of Conformity

CE

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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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 V1.0

Declaration of Conformity

CE

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

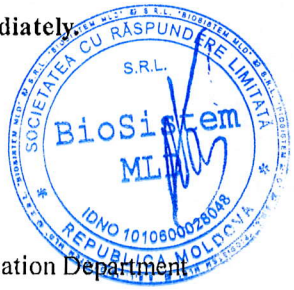
Classification:	Class A (According to Rule 5（a） of IVDR annex VIII)
Conformity Assessment Route:	Annex II and III of IVDR
GMDN code:	55854

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



Attachment of Declaration of Conformity: Applied Standards List-V1.0

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

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. BioSistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA

Declaration of Conformity V1.0

Declaration of Conformity

CE

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. Bio Sistem SRL IDNO 1016600028048 REPUBLICA MOLDOVA

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ BioSistem SRL MLD IDNO 1006600026048 REPUBLICA MOLDOVA

Declaration of Conformity V1.0

Declaration of Conformity

CE

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:	/
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Start of CE-Marking:	2022-4-19

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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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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)
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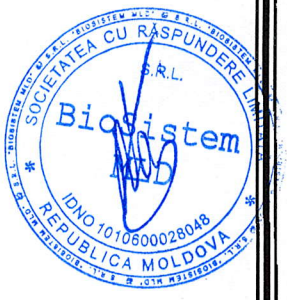
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices



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SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Certificate Holder: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

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

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

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

Report No.: **SH2405501**

Effective Date: **2024-08-28**

Expiry Date: **2026-06-30**

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Overall Scope Statement:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

仅供2024年备案使用

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SCC Accredited CB-MS OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor , Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and asseccories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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SCC Accredited CB-MS OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Facility(ies):

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

Facility Scopes:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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SCC Accredited CB-MS OCSM Accrédité CCN

America

认 证 证 书

证书号： QS5 044751 0140 Rev. 06

证书持有者： **深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦 518057

组织机构代码: 914403007084678371

认 证 标 志:

认 证 范 围: 证书范围见第2页

认证标准: ISO 9001:2015

TÜV SÜD America Inc.认证机构证明上述公司已经建立并保持满足上述所列标准要求的质量管理体系。

报告号: SH2405501

生效期: 2024-08-28

到期时间: 2026-06-30

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

日期， 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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SCC Accredited CB-MS OCSM Accrédité CCN

America

认 证 证 书

证书号： QS5 044751 0140 Rev. 06

认证范围：

设计和开发、生产、服务和分销：
医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、 全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

深圳迈瑞生物医疗电子股份有限公司

中国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
邮编：518057

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、 （全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

日期： 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

仅供2024年备案使用

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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认 证 证 书

证书号： QS5 044751 0140 Rev. 06

深圳迈瑞生物医疗电子股份有限公司
中国深圳市光明区南环大道1203号
邮编：518106

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

日期， 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 044751 0164 Rev. 06

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Service and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

Report No.: SH2405501

Valid from: 2024-08-15
Valid until: 2026-08-31

Date, 2024-08-15

Christoph Dicks
Head of Certification/Notified Body

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Certificate

No. Q5 044751 0164 Rev. 06

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments;
Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

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

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments;
Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

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For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System.

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TÜV SÜD Product Service

认 证 证 书

证书号. Q5 044751 0164 Rev. 06

证书持有者： **深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦

518057

认证标志：

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

认证范围： **设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息范围见附件)**

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见 www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

报告号： SH2405501

生效期： 2024-08-15

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发证日期, 2024-08-15

Christoph Dicks

Head of Certification/Notified Body

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TÜV SÜD Product Service

认 证 证 书

证书号. Q5 044751 0164 Rev. 06

认证标准：

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
医疗器械 - 质量管理体系 - 用于法规的要求

生产场地：

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市光明区南环大道1203号 518106

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

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证书号. Q5 044751 0164 Rev. 06

覆盖产品范围为:

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、 全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪），以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

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CIS-AL-LI373-13021291

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

26.02.2019

MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray")** manufacturer of Hematology analyzers, hereby authorize: **Biosistem-mld SRL,** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to submit bids and subsequently negotiate and sign Contracts for reagents and consumables for all auto-hematology analyzers supplied by company **Biosistem-mld SRL**.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

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

Best regards,

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

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com