ORDIN DE PLATA NR.: 2732 TIP.DOC. 1

DATA EMITERII:mar?i, 26 martie 2

PLATITI: 9100-00 LEI: Noua Mii Una Suta lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. suc."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) IMSP CS Ialoveni
CONTUL DE PLATI/CODUL IBAN
MD78VI000000225122431MDL
CODUL FISCAL :1013600022276 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.
CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1710852719638 din 28.03.2024

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:26/03/2024
DATA EXECUTARII:
SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAAEDi65avx+fXSldAAAAAQOLMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTI0MDEyNTExMzM1NloXDTI3MDEyNTExNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAAEDijjVd7aJ5r0rAAAAAQOKMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTI0MDEyNTExMzMzNVoXDTI3MDEyNTExNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2024.03.27 17:44:11 EET
Reason: MoldSign Signature
Location: Moldova

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1213048**

Din От **19.03.2024 12:13**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD

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

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **03.04.2024 12:13**

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

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **19.03.2024 12:13**

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

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

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

Дата предоставления 28.03.2023 14:26:11

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIÎO: 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: Dl (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

la

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: 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	3559998	3384131
	din care: 3.1. clădiri	081		
	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			
	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		
C.	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
	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		
D.	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: 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	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/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	27736628	36902223

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2022 pînă la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	38680547	40621876
din care: venituri din vînzarea 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 vînzări	016	4597	27472
Costul vînzărilor, total	020	24434231	22086174
din care: valoarea contabilă a produselor și mărfurilor vîndute	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 vînzărilor	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: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	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: 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	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

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				
	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				

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

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати
Сохранить

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

Версия для печати
Сохранить

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. 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

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

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

Lista fondatorilor Biosistem-mld SRL

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

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, bd. Moscovei, 14/1;

Scrisoare de informare

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

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

_____Vitalie Poiata

L.Ş.

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

BioSystems
REAGENTS & INSTRUMENTS

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard
Adenosine Deaminase (ADA) Standard
Albumin (Microalbuminuria) Standard
Anti-Streptolysin O (ASO) Standard
Antithrombin III Standard
Apolipoprotein A-I Standard
Apolipoprotein B Standard
b2-Microglobulin Standard
Bilirubin Standard
Biochemistry Calibrator
Biochemistry Calibrator (Human)
Cholesterol HDL/LDL Calibrator
CRP/CRP-hs Standard
Ferritin Standard
Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Prealbumin Standard
Protein Calibrators
Protein (urine) Standard
Rheumatoid Factors (RF) Standard

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct
a-Amylase-Pancreatic
Adenosine Deaminase (ADA)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
Aspartate Aminotransferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total)
Calcium-Arsenazo
Cholesterol
Cholesterol HDL direct
Cholesterol LDL direct
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
g-Glutamyltransferase (g-GT)
Glucose
Iron Ferrozine
Lactate dehydrogenase (LDH)
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Triglycerides
Urea/BUN UV
Uric acid

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)
Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)
Anti-Centromere B Antibodies (CENP-B)
Anti-Citrullinated Protein Antibodies (ACPA)
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)
Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:
AUTOIMMUNITY – INSTRUMENTS:

iPRO

RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide
Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon
TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/01	**BIOSYSTEMS S.A.** Costa Brava 30 08030 Barcelona Spain	Design, development, manufacture, distribution, installation and service of instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics.
/02	**BIOSYSTEMS, S.A.** Pol. Ind. Can Tapiolas Naves 12, 13, 21 y 22 08110 Montcada i Reixac (Barcelona) Spain	Reagent labelling and assembly. Storage of raw materials for instruments, instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. Dispatched of stored product.

2022-12-15

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**
Costa Brava 30
08030 Barcelona
Spain

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:
- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.
Storage of raw materials for instruments, instruments and reagents for:
- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched of stored product.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-12-19 until 2025-12-18.
First certification 1996

2022-12-15

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope: Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010, Montcada i Reixac – Barcelona, Spain	Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic.

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

BioSystems
REAGENTS & INSTRUMENTS

CERTIFICAT DE AUTORIZARE

Prin prezentul este autorizata

SRL Biosistem-MLD
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica Moldova produsele

BIOSYSTEMS SA
cu sediul C/Costa Brava 30
08030 Barcelona (Spain)

Xavier Palomar
Area Manager
27-April-2013

BioSystems
Costa Brava, 30
08030 BCN

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com

证书附件

标准	**ISO 9001:2015**
证书登记号码	**01 100 1832306**

号码	场地	认证范围
/01	(分证书) 迪瑞医疗科技股份有限公司 统一社会信用代码： 91220101605902656F 注册地址：中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号 邮编：130012 经营地址：同上述地址	体外诊断医疗器械的设计开发、生产和销售
/02	(分证书) 迪瑞医疗科技股份有限公司 统一社会信用代码： 91220101605902656F 注册地址：中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号 邮编：130012 经营地址：中华人民共和国吉林省长春市高新技术产业开发区宜居路 3333 号 邮编：130103	体外诊断医疗器械的设计开发、生产和销售

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准	**ISO 9001:2015**
证书登记号码	**01 100 1832306**

证书持有者：

迪瑞医疗科技股份有限公司
统一社会信用代码：91220101605902656F
注册地址：中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编：130012
经营地址：同上述地址

所包括场地已列于证书附件上

认证范围：

体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期：

证书有效期从 2021-05-03 至 2024-05-02。
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2018 年
本证书信息可在国家认证认可监督管理委员会官方网站上查询
http://www.cnca.gov.cn

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

认证证书

标准	**ISO 9001:2015**
证书登记号码	**01 100 1832306/01**

主证持有者：

迪瑞医疗科技股份有限公司
中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号
邮编：130012

场地：

(分证书) 迪瑞医疗科技股份有限公司
统一社会信用代码：91220101605902656F
注册地址：中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编：130012
经营地址：同上述地址

认证范围：

体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期：

证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。
此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
http://www.cnca.gov.cn

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

认证证书

标准	**ISO 9001:2015**
证书登记号码	**01 100 1832306/02**

主证持有者：

迪瑞医疗科技股份有限公司
中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号
邮编：130012

场地：

(分证书) 迪瑞医疗科技股份有限公司
统一社会信用代码：91220101605902656F
注册地址：中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编：130012
经营地址：中华人民共和国吉林省长春市
高新技术产业开发区宜居路 3333 号
邮编：130103

认证范围：

体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

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此证书须经过符合要求的监督审核保持有效。
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2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

No.	Location	Scope
/01	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: same as above	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems
/02	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: 3333 Yiju Street, New & High Tech. Development Zone, Changchun, 130103 Jilin, P. R. China	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

Certificate Holder: **Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Design and Development, Manufacture and Sales of in Vitro Diagnostic Medical Test Systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
First certification 2018
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1832306/01**

Organization:

Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone,
Changchun, 130012 Jilin, P.R. China

Site:

c/o **Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China
Operation Address: same as above

Scope:

Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate 01 100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306/02**

Organization: **Dirui Industrial Co., Ltd.**
95 Yunhe Street, New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China

Site: c/o **Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China
Operation Address: 3333 Yiju Street,
New & High Tech. Development Zone,
Changchun, 130103 Jilin, P. R. China

Scope: Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2101045-1
Organization:	Dirui Industrial Co., Ltd. 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P.R. China
Scope:	Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers and In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	190131562 110
Effective date:	2021-04-30
Expiry date:	2023-03-01
Issue date:	2021-05-08

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2101045-1

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone, Changchun,
130012 Jilin, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Dirui Industrial Co., Ltd. 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P.R. China	Design and Development, Manufacture of In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2101045-1

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone, Changchun,
130012 Jilin, P.R. China

The scope of certification also covers the following:

/02	c/o Dirui Industrial Co., Ltd. 3333 Yiju Street, New & High Tech. Development Zone, Changchun, 130103 Jilin, P.R. China	Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

CE Declaration of Conformity CE

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Dirui Industrial Co., Ltd.
95 Yunhe Street New& High Tech. Development Zone
Changchun Jilin 130012 P.R. China

Authorized Representative : Emergo Europe
Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis
IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture (where applicable)

DIRUI 1 ITEMS (GLU) **DIRUI 1 ITEMS (KET)** **DIRUI 1 ITEMS (PRO)**
DIRUI 2 ITEMS (PRO,GLU) **DIRUI 2 ITEMS(KET,GLU)**
DIRUI 3 ITEMS(PRO,PH,GLU) **DIRUI 3 ITEMS (PRO, KET,GLU)**
DIRUI 4 ITEMS (PRO,PH.BLD,GLU) **DIRUI 4 ITEMS (PRO,PH,SG,GLU)**
DIRUI 5 ITEMS (PRO,PH, BLD,KET,GLU)
DIRUI 8 ITEMS **DIRUI H8**
DIRUI 9 ITEMS
DIRUI A10 **DIRUI H10** **DIRUI E10** **DIRUI M10** **DIRUI H10-800**
DIRUI H11 **DIRUI H11-MA** **DIRUI H11-800**
DIRUI H11-800MA **DIRUI H12-800MA**
DIRUI H13-Cr **DIRUI H14-Ca**
DIRUI H13-Cr (H-800) **DIRUI H14-Ca (H-800)**

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:
Yu Ge
Dirui Industrial Co., Ltd.
于歌

(place and date of issue)

(name and signature or equivalent marking of authorized person)

CE

Declaration of Conformity

This is to state that Technical Documentation (CL001, rev. 2.0) for product(s)

Coaguometer

(Model:CA-01, CA-02)

(IVD products other than those covered by Annex II, IVD for self-testing and devices for Performance evaluation according to manufacturer's declaration)

Manufactured by

CLINDIAG SYSTEMS CO., LTD

No.29 Zhiyuan Road, Jurong Economic Development Zone,

Zhenjiang, Jiangsu Province, China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device

For and on behalf of
CLINDIAG SYSTEMS CO.,LTD.

Authorized Signature(s)

CLINDIAG SYSTEMS CO., LTD. 南京伦迪医疗技术有限公司

Mr. Xu Xin

General Manager

Valid from May, 2018 to May, 2023

CE

CLINDIAG
CLINDIAG SYSTEMS CO., LTD

地址：江苏省句容市经济开发区 Add: Jurong Economic and Delvelopment Zone
邮编：212400 Z.P: 212400
总机：+86 0511 80775555 Tel: +86 0511 80775555
传真：+86 0511 80770077 Fax: +86 0511 80770077

Manufacturer's Authorization

Date: 11 / 09 / 2019

To whom it may concern,

We, CLINDIAG SYSTEMS CO., LTD, locating at #29 Zhiyuan Road, Jurong Economic Development Zone, Zhenjiang, China, do hereby authorize: Biosistem-mld SRL, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to be our official representative for registration of all our products in Moldova.

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.

Yours faithfully,

For and on behalf of
CLINDIAG SYSTEMS CO.,LTD.

Authorized Signature(s)

Signed: Mu Zhicheng

In the capacity of: General Manager

Name: CLINDIAG SYSTEMS CO., LTD

Certificate CN19/42081

The management system of

CLINDIAG SYSTEMS CO., LTD.

29, Zhiyuan Road, Jurong Economic Development Zone,
Zhenjiang City, Jiangsu Province, 212400, P.R. China.

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Development, Production, Marketing and Service of Fully Automatic Biochemistry Analyzer, Semi-Automatic Biochemistry Analyzer, Haematology Analyzer, Microplate Reader, Coagulometer, Microplate Washer, Platelet Function Analyzer, Electrolyte Analyzer, Auto POCT Chemistry Analyzer

This certificate is valid from 4 June 2019 until 3 June 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 March 2022
Issue 1. Certified since 4 June 2019

Multiple certificates have been issued for this scope
The main certificate is numbered CN19/42078.00

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

REGISTRATION NO. 04719Q10805R0S

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Clindiag Systems Co., Ltd.

Registered Address: No.29 Zhiyuan Road, Jurong Economic Development Zone, Jiangsu Province, P.R.China Postcode: 212400
Manufacturing Address: No.29 Zhiyuan Road, Jurong Economic Development Zone, Jiangsu Province, P.R.China

Has been assessed and conformed to the following standard(s)

GB/T19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of Semi-Automatic Biochemistry Analyzer, Coagulometer Analyzer, Semi-Automatic Electrolyte Analyzer, Semi-Automatic Microplate Reader, Microplate Washer, Automatic Urine Analyzer And Urine Test Strips, Fully Automatic Biochemistry Analyzer, Fully Automatic Hematology Analyzer,

Date of issue: July 16, 2019
Date of expiry: July 15, 2024

Director: Zhuangchen

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

MANAGEMENT SYSTEM
CNAS C047 - Q

Note:The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or the Website of CMD (www.cmdc.com.cn).

BioSystems
REAGENTS & INSTRUMENTS

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

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

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

BioSystems
Costa Brava, 30
08030 BCN

Xavier Palomar
Area Manager
27-April-2011

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com

DIAMOND®
DIAGNOSTICS

Diamond Diagnostics Inc.
333 Fiske Street • Holliston, MA 01746 USA
508.429.0450 • Fax: 508.429.0452
diamonddiagnostics.com

LETTER OF AUTHORIZATION

Date: September 10, 2019

To whom it may concern,

Diamond Diagnostics Inc., (hereinafter referred to as DD), having its registered office at 333 Fiske Street, Holliston, MA 01746, USA, Biosistem-mld SRL, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to participate on any tender with the entire range of the SmartLyte and its consumables (hereinafter referred to as PRODUCTS) and as an official representative for registration of all our products in Moldova.

The Letter of Authorization is valid until 31st of December 2023, but may be freely withdrawn at any time.

Yours sincerely,

Eli Gallo
Regional Sales Manager
Diamond Diagnostics

DIAMOND
DIAGNOSTICS
Diamond Diagnostics, Inc.
333 Fiske Street
Holliston, MA 01746 USA
508.429.0450 • Fax: 508.429.0452
www.diamonddiagnostics.com

DIAMOND
DIAGNOSTICS

DECLARATION OF CONFORMITY

Diamond Diagnostics, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics, Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Uniós 98/79/EC irányelvben foglaltaknak

Diamond Diagnostics, Inc. versichert und erklä hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics, Inc. assure et declare par la présente que le(s) produit(s) listé(s) c- dessous sont conformes aux exigencies de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics, Inc. asegura y declara que los productos listados a continuación cumplen con los requisites establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics, Inc确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics, Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics, Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/ЕС Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمة
ان شركة دايموند دياغنوستكس تصرح و تؤكد أن

Diamond Diagnostics, Inc. dichiara ed assicura che I prodotti qui elecati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispostivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 产品（S）/ Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) ;

Diamond Electrolyte Analyzers
Model: GEMLYTE, SMARTLYTE, SMARTLYTE PLUS, CARELYTE, CARELYTE PLUS, PROLYTE

Authorized Officer: Kathy Fisher _____ **Date:** 30 April, 2018
Kathy Fisher
Global Quality Manager

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure
Annex III, Self-Declared

Manufacturer's Name: Diamond Diagnostics, Inc. (USA)
Manufacturer's Address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

CE

MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT
CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of

Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és klinikai diagnosztikai készülékek felújítása

meets the requirements of the standard for the following activities:
the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

MSZ EN ISO 13485:2016 (ISO 13485:2016)

A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.
A tanúsítási okirat száma / Reg. number: **503/1342(2)**
Budapest, **2020. december 21.**
Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**

Pónyai György
ügyvezető igazgató

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.
Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **21-12-2020**
First issued on: **26-06-2014**
Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: **HU-MSZT-503/1342(2)-1262(2)**

Alex Stoichitoiu
President of IQNet

György Pónyai
General Director of MSZT

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* *NYCE*-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

NAH-4-0044/2018
IRÁNYÍTÁSI RENDSZEREKET
TANÚSÍTÓ SZERVEZET

THE INTERNATIONAL CERTIFICATION NETWORK

MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION
H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT
CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of

Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.
Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és klinikai diagnosztikai készülékek felújítása

meets the requirements of the standard for the following activities:
the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

MSZ EN ISO 9001:2015 (ISO 9001:2015)

A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.
A tanúsítási okirat száma / Reg. number: **503/1341(2)**
Budapest, **2020. december 21.**
Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**

Pónyai György
ügyvezető igazgató

MSZT CERT

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.
Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **21-12-2020**
First issued on: **26-06-2014**
Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: **HU-MSZT-503/1341(2)-1261(2)**

Alex Stoichitoiu
President of IQNet

György Pónyai
General Director of MSZT

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

DIAMOND
DIAGNOSTICS

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Uniós 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklä hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) c- dessous sont conformes aux exigencies de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisites establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمة
ان شركة دايموند دياغنوستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che I prodotti qui elecati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispostivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 产品 (S) / Produto(s) / Продукт (ы) / (ق) المنتج / Prodott(i) ;

Model: Mission Controls

Quality Controls:

DD-92001 Mission Control Level 1
DD-92002 Mission Control Level 2
DD-92003 Mission Control Level 3
DD-92004 Mission Control Level 4
DD-92123 Mission Control Level 1-2-3

DD-92900 Mission Complete Linearity Control
DD-96001 Mission Trinity B Level 1
DD-96002 Mission Trinity B Level 2
DD-96003 Mission Trinity B Level 3
DD-96123 Mission Trinity B Level 1-2-3

DD-97001 Mission Trinity R Level 1
DD-97002 Mission Trinity R Level 2
DD-97003 Mission Trinity R Level 3
DD-97123 Mission Trinity R Level 1-2-3

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Officer: Kathy Fisher **Date:** 28 December, 2017
Kathy Fisher
Global Quality Manager

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure
Annex III, Self-Declared

CE

Manufacturer's name: Diamond Diagnostics Inc. (USA)
Manufacturer's address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

DIAMOND
DIAGNOSTICS

DECLARATION OF CONFORMITY

Diamond Diagnostics, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics, Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Uniós 98/79/EC irányelvben foglaltaknak

Diamond Diagnostics, Inc. versichert und erklä hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics, Inc. assure et declare par la présente que le(s) produit(s) listé(s) c- dessous sont conformes aux exigencies de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics, Inc. asegura y declara que los productos listados a continuación cumplen con los requisites establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics, Inc确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics, Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics, Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/ЕС Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمة
ان شركة دايموند دياغنوستكس تصرح و تؤكد أن

Diamond Diagnostics, Inc. dichiara ed assicura che I prodotti qui elecati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispostivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 产品（S）/ Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) ;

Diamond Electrolyte Analyzers
Model: GEMLYTE, SMARTLYTE, SMARTLYTE PLUS, CARELYTE, CARELYTE PLUS, PROLYTE

Authorized Officer: Kathy Fisher _____ **Date:** 30 April, 2018
Kathy Fisher
Global Quality Manager

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure
Annex III, Self-Declared

Manufacturer's Name: Diamond Diagnostics, Inc. (USA)
Manufacturer's Address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

CE

DIAMOND
DIAGNOSTICS

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Uniós 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklä hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) c- dessous sont conformes aux exigencies de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisites establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/ЕС Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمة
ان شركة دايموند دياغنوستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che I prodotti qui elecati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispostivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 产品 (S) / Produto(s) / Продукт (ы) / المنتج (ق) / Prodott(i) ;

Model: Diamond Diagnostics Smartlyte/CareLyte/Gemlyte

Reagent & Controls:

AV-BP5186D Fluid Pack
AV-BP0380D Electrode Conditioning Solution
AV-BP0521D Deproteinizer
AV-BP0344D Urine Diluent
AV-BP1025D ISE Cleaning Solution

Electrodes & Accessories:

AV-BP0413D Na+ Electrode
AV-BP0359D K+ Electrode
AV-BP0570D Cl- Electrode
AV-BP0360D Ca++ Electrode
AV-BP0962D Li+ Electrode
AV-BP5026D Reference Electrode
AV-BP5027D Peristaltic Pump Tubing
AV-BP5006D Sample Probe
AV-BP5036D Sample Sensor
AV-BP5019D Reference Electrode Housing
AV-BP5025D Printer Paper
AV-BP5193D Pinch Valve Tubing Kit
AV-BP5014D Shutdown Kit
AV-BP5194D Startup Kit
AV-BP9043D Fillport Assembly

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized Officer: Kathy Fisher **Date:** 30 April, 2018
Kathy Fisher
Global Quality Manager

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Manufacturer's name: Diamond Diagnostics Inc. (USA)
Manufacturer's address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

Conformity Assessment Procedure
Annex III, Self-Declared

CE

BIOSYSTEMS

BioSystems
REAGENTS & INSTRUMENTS

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

Mr. Nasedchin Alexandr

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

May 18-22, Moscow 2009

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

Sergey Vasiliyev

"БИОСИСТЕМС, С.А."
Испания
"BIOSYSTEMS, S.A."

BIOSYSTEMS

BioSystems
REAGENTS & INSTRUMENTS

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

Mr. Poiata Vitalie

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

May 18-22, Moscow 2009

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

Sergey Vasiliyev

"БИОСИСТЕМС, С.А."
Испания
"BIOSYSTEMS, S.A."

Mindray Medical Russia

Сертификат

Poiata Vitalie

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-5150
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

"Миндрей Медика Рус" Limited Liability Company Mindray Medical Rus

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.

Mindray Medical Russia

Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-5150
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.

CLINDIAG
Clindiag Systems BVBA

Steenberg 66
Ninove
BELGIUM

18.12.2014

To: Whom it may concern

SERVICE TRAINING CERTIFICATE

We Clindiag Sustems BVBA, located Steenberg 66, Ninove 9401, who are official manufacturers of the Clindiag laboratory products, having own Clindiag group factories at several countries, do hereby authorize Mr. Alexandr Nasedchin the representative of Biosistem-mld SRL located at Albisoara Str, 16/1 Chisinau, Moldova to provide the technical support of the Clindiag laboratory analyzers as per the following list:

1. Semi auto chemistry analyzers SA-20 & SA-10.
2. Auto chemistry analyzers FA-200 & FA-300.
3. Coagulation analyzers CA-01& CA-02.

Romain Cieters
Manager Clindiag

CLINDIAG
Clindiag Systems BVBA
Steenberg 66
9401 Ninove - BELGIUM
Tel.: 054/250.936
Fax: 054/243.058
ON: 806.140.472

CLINDIAG
Clindiag Systems BVBA

Steenberg 66
Ninove
BELGIUM

18.12.2014

To: Whom it may concern

SERVICE TRAINING CERTIFICATE

We Clindiag Sustems BVBA, located Steenberg 66, Ninove 9401, who are official manufacturers of the Clindiag laboratory products, having own Clindiag group factories at several countries, do hereby authorize Mister Poiata Vitalie Vasile the representative of Biosistem-mld SRL located at Albisoara Str, 16/1 Chisinau, Moldova to provide the technical support of the Clindiag laboratory analyzers as per the following list:

1. Semi auto chemistry analyzers SA-20 & SA-10.
2. Auto chemistry analyzers FA-200 & FA-300.
3. Coagulation analyzers CA-01& CA-02.

Romain Cieters
Manager Clindiag

CLINDIAG
Clindiag Systems BVBA
Steenberg 66
9401 Ninove - BELGIUM
Tel.: 054/250.936
Fax: 054/243.058
ON: 806.140.472

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

Service Training Certificate

To: Biosistem-mld SRL

Date: 30-07-2015

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 confirm that,

Mr. Vitalie Poiata the representative of Biosistem-mld SRL has attended the course of technical training devoted to Urine analyzers H-100, H-500, H-800.

For an on behalf of Dirui Industrial Co., LTD

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

Dima Ji
International Marketing & Sales Director
DIRUI INDUSTRTIAL CO.,LTD

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

Service Training Certificate

To: Biosistem-mld SRL

Date: 30-07-2015

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 confirm that,

Nasedchin Alexandr, representative of Biosistem-mld SRL has attended the course of technical training devoted to Urine analyzers H-100, H-500, H-800.

For an on behalf of Dirui Industrial Co., LTD

Dima Ji
International Marketing & Sales Director
DIRUI INDUSTRTIAL CO.,LTD

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

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

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

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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:

TÜV SÜD ISO 9001

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.: **SH2005501**

Effective Date: **2020-08-12**

Expiry Date: **2023-06-30**

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic 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, 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 Immunossay 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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 and Distribution of Medical Electronic 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, 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 Immunossay 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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 and Distribution of Medical Electronic 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, 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 Immunossay 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

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
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development,
production 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). See also notes overleaf.

Report No.: SH2005501

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-07-24

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

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,
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,
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit,
Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag.

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CIS-DL-LI373-66601931

December 29th, 2020

LETTER OF DECLARATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray")** manufacturer of Hematology analyzer **BC-5150,** do hereby declare that:

The following reagents:

- 105-004045-00 M-52D Diluent
- 105-003724-00 M-52DIFF Lyse
- 105-004307-00 M-52LH Lyse
- 105-002225-00 M-68 Probe Cleanser
- 105-003233-00 BC-5D High/Normal/Low/EN3ml*3

Are manufactured by our company exclusively for the use with the closed-system BC-5150 Hematology Analyzers. The usage of reagents is also described in the user manual of the analyzer at the point: "*2.7. Reagents, Controls and Calibrators*", *page 2-12.*

Sincerely yours,

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

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