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ORDIN DE PLATA NR.: 486 TIP.DOC. 1 :
DATA EMITERII:24 noiembrie 2020 :
=====:
PLATITI: 3100-00 LEI: Trei Mii Una Suta lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) I.M.S.P. AS CONTUL DE PLATI/CODUL IBAN :
OCIATIA MEDICALA TERITORIALA MD54TRPCBW518430A00371AA :
BUIUCANI CODUL FISCAL :1003600153131 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat :TREZMD2X :
=====:
DESTINATIA PLATII:/P102/3100,00 Pentru g: TIPUL TRANSFERULUI :
arantia pentru oferta la procedura de ac: NORMAL/URGENT :N:
hizi?ie publica nr. ocds-b3wdp1-MD-16057: :
8738921 din 08.12.2020. :
:
:
: L.S. :
=====:
CODUL TRANZACTIEI:101: :
DATA PRIMIRII:24/11/2020 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBEowggRGMIIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTeQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxZjA :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWR1Y29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT :
:
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNTURA PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

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

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei
care a eliberat certificatul

L. Svirepova
semnătura

MD 0101250





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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

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

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

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

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;

3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;

4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;

5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;

6 Consultații în domeniul sistemelor de calcul.

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

1. POIATA VITALIE , IDNP 0983103892591

cota 1803.60 lei, ce constituie 33,4 %

2. NASEDCHIN ALEXANDR , IDNP 2002001070747

cota 1798.20 lei, ce constituie 33,3 %

3. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

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

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2030318**

din
от **02.12.2020**

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:
0,00 lei/лей.

4. Valabil pînă la / Действителен до 17.12.2020

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Rîșcani a DGAF mun.Chisinau Funcția/Dолжность	 Semnătura/Подпись	Viorica CĂUȘ Numele și prenumele/Фамилия и имя
L.Ș/ М.П. Executor: Claudia GOJAN Numele și prenumele/Фамилия и имя		

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 02.12.2020 ora 15:56:58
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,42)

Data prezentării 21.05.2020 10:13:29
SITUATIILE FINANCIARE

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

2019 pentru perioada 01.01.2018 - 31.12.2019 de lichidare

BIROUL NAȚIONAL DE STATISTICĂ

Entitate: BUSISTEM MLD S.R.L.
Sediu: SEC. RISCANI, STR. ALBISOARA NR.16 BL.1 OF.7
Raionul(municipiul): 106, DDF RISCANI
Satul(communa):
Strada: SEC. RISCANI, STR. ALBISOARA NR.16 BL.1 OF.7
Cod postal: 2001
Cod CUATM: 2150, SEC. RISCANI
Activitatea principala: 6464, Comerț cu ridicata al produselor farmaceutice
Forma proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată
Cod CUIO: 40711790
Codul fiscal: 1010600028048
WEB:
Numele și coordonatele al contabilului-sef: Nasedchin Alexandr
Telefon: +37322808719
Numărul mediu scrisor al personalului in perioada precedenta: g persoane.

Unitatea de masura: leu

Notă informativă privind veniturile și cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzari	010		
Alte venituri din activitatea operationala	020		
Venituri din alte activitati	030		
Total venituri (rd.010 + rd.020 + rd.030)	040		
Variatia stocurilor	050		
Costul vinzarilor mărfurilor vândute	060		
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080		
Contributi de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090		
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100		
Alte cheltuieli	110		
Cheltuieli din alte activitati	120		
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130		
Profit (pierdere) pina la impozitare (rd.040 - rd.130)	140		
Cheltuieli privind impozitul pe venit	150		
Profit (pierdere) net al perioadei de gestiune (rd.140 - rd.150)	160		

BILANȚUL

la

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrsitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizari necorporale	010	1137	487
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	938614	2208593
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobiliare	090		
	Creante pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate (rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	939751	2209080
	Active circulante			
	Materiale	140		6209

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrsitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160	51520	47842
	Productia in curs de executie si produse	170		
	Mărfuri	180	4809995	5710647
	Creante comerciale	190	5528804	4327729
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	2496545	1647170
	Creante ale bugetului	220	26401	166486
	Creante ale personalului	230		
	Alte creante curente	240		
	Numerar in casierie si la conturi curente	250	9066228	8911899
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	3712	742
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	21983205	20828724
	Total active (rd.130 + rd.300)	310	22922956	23037804
	Capital propriu			
	Capital social si suplimentar	320	5400	5400
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340	x	
	Profit net nepartizat (pierdere neacoperita) al anilor precedenti	350	18182879	12119049
	Profit net (pierdere neta) al perioadei de gestiune	360		8902436
	Profit utilizat al perioadei de gestiune	370	x	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	18188279	21026865
4.	Datorii pe termen lung			
	Credite bancare pe termen lung	400		
	Imprumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
	Datorii curente			
	Credite bancare pe termen scurt	450		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	3883519	1331928
	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	135390	159545
	Datorii fata de personal	500	152404	2913
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	492060	434590
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	71304	81963
5.	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	4734677	2010939
	Total pasive (rd.390 + rd.440 + rd.580)	590	22922956	23037804

SITUATIA DE PROFIT SI PIERDERE

de la pina la

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzari	010	27523075	27319617
Costul vinzarilor	020	15709392	15672962
Profit brut (pierdere bruta) (rd.010 - rd.020)	030	11813683	11646655
Alte venituri din activitatea operationala	040		28586
Cheltuieli de distribuire	050	46862	16306
Cheltuieli administrative	060	729327	964136

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Alte cheltuieli din activitatea operationala	070	384100	417394
Rezultatul din activitatea operationala: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10653394	10277405
Rezultatul din alte activitati: profit (pierdere)	090	10777	195996
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	10664171	10081409
Cheltuieli privind impozitul pe venit	110	1291160	1178993
Profit net (pierdere neta) al perioadei de gestiune (rd.100 - rd.110)	120	9373011	8902416

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

de la pina la

Anexa 3

Nr. dno	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorari	Diminuari	Sold la sfîrsitul perioadei de gestiune
1	2	3	4	5	6	7
1	Capital social si suplimentar					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	0	0	0	0
	Capital neînregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
	Rezerve					
	Capital de rezerva	070				
	Rezerve statutare	080				
2	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
	Profit nerepartizat (pierdere neacoperita)					
	Corectii ale rezultatelor anilor precedenti	110	X			
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	120				
	Profit net (pierdere neta) al perioadei de gestiune	130	X			
	Profit utilizat al perioadei de gestiune	140	X			
	Rezultatul din tranzitia la nolle reglementari contabile	150				
	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160				
	Alte elemente de capital propriu, din care	170				
4	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180				

SITUATIA FLUXURILOR DE NUMERAR

de la pina la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea operationala			
Incasari din vânzari	010		
Plati pentru stocuri si servicii procurate	020		
Plati catre angajati si organe de asigurare sociala si medicala	030		
Dobînzî platite	040		
Plata impozitului pe venit	050		
Alte incasari	060		
Alte plati	070		
Fluxul net de numerar din activitatea operationala (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investitii			
Incasari din vanzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobînzî incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxul net de numerar din activitatea de investitii (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)			
140			
Fluxuri de numerar din activitatea financiara			
Incasari sub forma de credite si imprumuturi	150		
Plati aferente rambursarii creditelor si imprumuturilor	160		
Dividende platite	170		
Incasari din operatiuni de capital	180		
Alte incasari (plati)	190		
Fluxul net de numerar din activitatea financiara (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferente de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrsitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Date generale

Anexa 6

- Certificat de înregistrare a entității, eliberat de Camera Înregistrării de Stat.
- Numar de înregistrare Data Înregistrării Seria Numar
- Capital social înregistrat de Camera Înregistrării de Stat:
data , suma lei, inclusiv:
a) cota statutului lei,
b) cota detinatorilor a cel puțin 20% Incease lei.
Modificari ulterioare:
a) , suma lei, inclusiv cota statutului lei,
b) , suma lei, inclusiv cota statutului lei.
- Entitatile, activitatea carora necesita licenta, indica:
Licenta in vigoare:

Nr. Ord.	Numar	Data eliberarii	Termen de valabilitate	Tipul de activitate	Organul care a eliberat licenta
1					
- Numarul mediu scrisor al personalului in perioada de gestiune g persoane, inclusiv pe categorii:
1) personal administrativ g persoane,
2) muncitori persoane.
- Numarul personalului la 31 decembrie 2019 g persoane.
- Remunerarea personalului entitatii in perioada de gestiune 326523 lei.
- Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.
- Avansurile si creditile acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.
1) valoarea de gaj lei,
2) valoarea contabila lei.
- Numarul actiunilor ordinare a finelc perioadei de gestiune unitati.
- Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
1) profit lei,
2) pierdere lei.
- Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:
1) platite lei,
2) planificate pentru plata lei.
- Valuta straina disponibila, recalculata in moneda nationala a Republicii Moldova - total lei, inclusiv lei, denumirea si codul valutei:

Nr. Ord.	lei	denumirea	codul valutei
1			
- Numerar legat - total lei.
In indurilie, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:
a) la numarator - valoarea de gaj;
b) la numitor - valoarea contabila

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii pe termen lung aferente fondatorilor nerezidenti

Tabelul 1

Indicatori	Cod rd./ cod tara	Sold la începutul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfîrsitul perioadei de gestiune
			Intrari / majorari	iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total						
010						
Creante comerciale, inclusiv pe tari:						
020						
1	2	3	4	5	6	7

1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Datorii pe termen lung - total	060					
Datorii comerciale, inclusiv pe tari:	070					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100
Col.7 = col.3+col.4-col.5-col.6

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor						
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, inclusiv pe tari:	020					
1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Depozite, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	060					
1	2	3	4	5	6	7
Datorii pe termen lung - total	070					
Datorii comerciale, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	090					
1	2	3	4	5	6	7

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.9+10= col.(3+4) + col.5 - col.7 ± col.8

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60
Rd.070= rd.080 + rd.090 + rd.100 + +rd.110
Col.7 = col.3+col.4-col.5-col.6

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti						
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari
					Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an
						Termenul expirat mai mult de un an
1	2	3	4	5	6	7
Creante si investitii financiare curente - total	010					
Creante comerciale, inclusiv pe tari:	020					
1	2	3	4	5	6	7
Avansuri acordate, inclusiv pe tari:	030					
1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040					
1	2	3	4	5	6	7
Alte creante si investitii financiare, inclusiv pe tari:	050					
1	2	3	4	5	6	7
Datorii curente - total	060					
Datorii comerciale, inclusiv pe tari:	070					
1	2	3	4	5	6	7
Avansuri primite, inclusiv pe tari:	080					
1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090					
1	2	3	4	5	6	7
Datorii privind dividenzele calculate, inclusiv pe tari:	100					
1	2	3	4	5	6	7
Alte datorii, inclusiv pe tari:	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor								
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an
								Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9
Creante si investitii financiare curente - total	010							
Creante comerciale, inclusiv pe tari:	020							
1	2	3	4	5	6	7	8	9
Avansuri acordate, inclusiv pe tari:	030							
1	2	3	4	5	6	7	8	9
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040							
1	2	3	4	5	6	7	8	9
Depozite, inclusiv pe tari:	050							
1	2	3	4	5	6	7	8	9
Alte creante si investitii financiare, inclusiv pe tari:	060							
1	2	3	4	5	6	7	8	9
Datorii curente - total	070							
Datorii comerciale, inclusiv pe tari:	080							
1	2	3	4	5	6	7	8	9
Avansuri primite, inclusiv pe tari:	090							
1	2	3	4	5	6	7	8	9
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100							
1	2	3	4	5	6	7	8	9
Alte datorii, inclusiv pe tari:	110							

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social					
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Investitii financiare	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, inclusiv pe tari:	020				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, inclusiv pe tari:	030				
1	2	3	4	5	6

1	2	3	4	5	6
Capital social	040				
Cote de participatie si actiuni de pina la 10% inclusiv, inclusiv pe tari:	050				
1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, inclusiv pe tari:	060				

Rd.010= rd.020 + rd.030
Rd.040= rd.050 + rd.060
Col.6 = col.3+col.4-col.5

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii				
Indicatori	Cod rd./cod tara	Perioada de gestiune		
		precedenta	curenta	
1	2	3	4	
Venituri - total	010			
Venituri aferente bunurilor procurate si vandute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	020			
1	2	3	4	
Venituri din dobinzi aferente activitatii operationale si altor activitati, inclusiv pe tari:	030			
1	2	3	4	
Venituri din dividende si participati in alte entitati,inclusiv pe tari:	040			
1	2	3	4	
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, inclusiv pe tari:	050			
1	2	3	4	
Alte venituri, inclusiv pe tari:	060			
1	2	3	4	
Cheltuieli - total	070			
Cheltuieli aferente bunurilor procurate si vandute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	080			
1	2	3	4	
Cheltuieli privind dobinzile, inclusiv pe tari:	090			
1	2	3	4	
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, inclusiv pe tari:	100			
1	2	3	4	
Alte cheltuieli, inclusiv pe tari:	110			

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Anexa 9

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere					
Indicatori	Cod rd./cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, inclusiv pe tari:	010				
1	2	3	4	5	6

6/12/2020

View BNS receipt | Declaratia electronica

Versiune de imprimare

Salvare

Recipisa 2

Respondent

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

A prezentat raportul: RSF1

Pentru perioada fiscala: A/2019

Data prezentarii: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.05.2020 10:13:29

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.

Col.6 = col.3+col.4-col.5

Informațiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
A	1	2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200								
2.1 brevete și mărci	210								
2.2. licențe de activitate	220								
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		x					x	
5. Mijloace fixe, total din care:	500								
5.1. clădiri	510								
5.2. construcții speciale	520								
5.3. mașini, utilaje, instalații de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente și inventar	550								
5.6. costuri ulterioare aferente obiectelor neluate în bilanș	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590								
6. Resurse minerale	600								
7. Investiții imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entității*

* conform art.36 din Legea contabilității

Documente atașate - Notă explicativă (fișierul pdf)

Blisistem 2019.pdf

6/12/2020

Afișează recipisa | Declaratia electronica

Versiune de imprimare

Salvare

Recipisa

Respondent

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

A prezentat raportul: RSF1

Pentru perioada fiscala: A/2019

Data prezentarii: 31.03.2020

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 31.03.2020 17:42:37

https://declaratie-electronica.fisc.md/ro/declaration/11542429/receipt-bns?print=1

1/1



BIOSISTEM-MLD S.R.L.

c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea

Procedurii de achiziție ocde-b3wdp1-MD-1605787389218

din 08.12.2020

din cadrul IMSP AMT Buiucani

Declarație

Prin prezenta, SRL „Biosistem-mld”, declara ca

- Include suportul științific
- Dispune de persoane disponibile, instruite și autorizate de producătorul utilajului pentru a oferi servicii de suport tehnic, mentenanță, reparație în caz de necesitate
- În caz de necesitate, va prezenta mostre timp de 1 zi de la înștiințare
- Bunurile oferite în cadrul ofertei pentru această procedură de achiziție publică sunt înregistrate în registrul de stat al dispozitivelor medicale sau urmează a fi înregistrate până la momentul livrării. Acest fapt poate fi verificat pe platforma Agenției Medicamentului și Dispozitivelor Medicale.

_____ Vitalie Poiata

L.Ș.

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



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



Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management
System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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



AUTOIMMUNITY – ELISA:

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

Certificate

Standard **ISO 9001:2015**

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

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

Scope: Design, development, manufacture, distribution, servicing of:
-Instruments and reagents for clinical diagnostic.
-Instruments and reagents for agro-alimentary analysis.
Distribution and service of reagents and instruments for veterinary diagnosis.

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

Validity: The certificate is valid from 2019-12-19 until 2022-12-18.
First certification 1996

2019-12-20

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/02	BIOSYSTEMS S.A. Pol. Ind. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labeling and assembly of reagent. Storage, and shipping of: - Instruments and reagents for diagnosis and reagents for clinical diagnosis.- Instruments and reagents for agri- food analysis.- Instruments and reagents for veterinary diagnosis.

2019-12-20



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture, distribution and
servicing of instruments and reagents for
clinical diagnostic
(see attachment for sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-08
Certificate Registration No.: SX 60145545 0001
An audit was performed. Report No.: 28300434 004
This Certificate is valid until: 2022-12-12

Certification Body



Date 2020-01-08



D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60145545 0001
Report No.: 28300434 004

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

Scope:

Site included:

Polígono Industrial Can Tapioles
Naves 7, 12 y 13
08110 Montcada i Reixac
Spain

Activity: Labelling and assembling of reagents,
warehousing and shipment of instruments
and reagents for clinical diagnostic

Certification Body



Date: 2020-01-08

D. Swiatko

Declaration of Conformity



Manufacturer: Beijing Precil Instrument Co., Ltd.
2F East 5 Building, Qunying kejiyuan, Shangdi
Information Base, Haidian District, Beijing 100085,
China

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

Product: Auto Coagulation Analyzer

Model: C3100

Consumables : Auto Cuvettes
Probe Cleanser
Cleanser

Classification: Others(Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

Standard applied:

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

Start of CE-Marking: 2016-09-01

Place, Date: Beijing, 2016-09-01

Signature:

Name of Authorized Signatory: Zhang Yaohui

Position Held in Company: Management Representative

Applied Standards List

Product: Auto Coagulation Analyzer

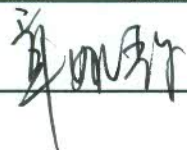
Applied Standards:

EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN13640:2002	Stability testing of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-1)
EN ISO 15193:2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin
EN ISO 15194:2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
EN ISO 17511:2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
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 CORR: January 31, 2012
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements IEC 61326-1:2005
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 IEC 61326-2-6:2005
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements IEC 61010-1:2001
EN 61010-2-081:2002+A1:2003	Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2001
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)

Drafted by:



Checked by:





America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

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 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA,
MHLW / PMDA. See attached for listing of specific
regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

65-467-1304

Effective Date:

2019-08-26

Expiry Date:

2021-10-23

Page 1 of 4

Date of Issue: 2019-11-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Overall Scope Statement:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 2 of 4

Date of Issue: 2019-11-25



(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

CERTIFICATE

No. QS6 044751 0135 Rev. 01

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

Facility Scopes:

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 and Distribution of
Medical Electronic Equipment (including Patient Monitor and
Accessories (NIBP House, NIBP Cuff, Sensor Cables including
SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG
Cables and Leadsets, Temperature Probe, Probe Cover),
Vital Signs Monitor, Center Monitoring System, Telemetry
Monitoring System, Pulse Oximeter, Defibrillator / Monitor
and Accessories, Electrocardiograph, Anesthesia Machine
and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic
Equipment, Ultrasonic Transducer, Hematology Analyzer,
Clinical Chemistry Analyzer, Microplate Reader, Microplate
Washer for In-Vitro Diagnostic Use, Chemiluminescence
Immunossay Analyzer, Flow Cytometer, Auto Sample
Processing System, Auto Slide Maker and Stainer;) Reagents
for Hematology Analyzer, Reagents for Clinical Chemistry
Analyzer, Chemiluminescence Immunoassay Reagents,
Chemiluminescence Immunoassav Calibrators and Controls;
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit, Reusable
Breathing Circuit, Heat and Moisture Exchanger, Filter,
Breathing Bag
DUNS No: 65-467-1304

Page 3 of 4

Date of Issue: 2019-11-25



(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

No. QS6 044751 0135 Rev. 01

1203 Nanhuan Avenue, Guangming District, 518106, Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 54-459-5743

Gwen Thodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS



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:



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

Page 1 of 4

Date of Issue: 2020-08-20

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



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

Page 2 of 4

Date of Issue: 2020-08-20

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



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

Page 3 of 4

Date of Issue: 2020-08-20

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



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

Page 4 of 4

Date of Issue: 2020-08-20

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

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

16.10.2020

MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("**Mindray**") manufacturer of Coagulation analyzer **C-3100**, hereby authorize: **Biosistem-mld SRL** with business office at Albisoara 16/1 ap.7 , Chişinău, R.Moldova, to as the **exclusive one company** to submit a bid, and subsequently negotiate and sign the Contract against for procurement of reagents, consumables and spare parts for the Coagulation analyzer C-3100 for the Tender organized by IMSP AMT Buiucani for the year 2021.

This authorization is valid from the date of issuance up to conclusion of the tender project. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any further compensation to You.

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.

Very truly yours,



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

CERTIFICATE

This is to certify that

Poiata Vitalie

Biosistem-mld SRL , Moldova

For Successfully Completed the course

Coagulation

C-3100

Technical Training

2018/07/28-2018/07/29

Q.H.Li
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date:2018.07.29

CERTIFICATE

This is to certify that

Nasedchin Alexandr

Biosistem-mld SRL , Moldova

For Successfully Completed the course

Coagulation

C-3100

Technical Training

2018/07/28-2018/07/29

Q.H.Li
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date:2018.07.29