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ORDIN DE PLATA NR.: 599 TIP.DOC. 1 :
DATA EMITERII:23 februarie 2021 :
=====:
PLATITI: 6000-00 LEI: Sase Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML00000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP CS Ial CONTUL DE PLATI/CODUL IBAN :
oveni MD78VI000000225122431MDL :
CODUL FISCAL :1013600022276 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
B.C."VICTORIABANK"S.A. :VICBMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la licitatie publica nr. 2103622: NORMAL/URGENT :N:
9 din 04.03.2021 :
:
:
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:23/02/2021 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGYwYJKoZiIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSib:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq:
Sib3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZiIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSib3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
Sib3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
-----:
MOTIVUL REFUZULUI : L.S. :
-----:



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. 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.
№ **A2102242**

din
от **16.02.2021**

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.	101060028048
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 până la / Действителен до 03.03.2021

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

Șef DDF Rîșcani
a DGAF mun.Chișinău

Funcția/Должность

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”// 16.02.2021 ora 14:09:46
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,44)

2019 pentru perioada 01.01.2019 - 31.12.2019 de lichidare

BIROUL NAȚIONAL DE STATISTICĂ

Entitatea: BIOSISTEM MLD S.R.L.
 Sediul: SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
 Raionul(municipiul): 106, DDF RISCANI
 Satul(comuna):
 Strada: SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
 Cod postal: 2001
 Cod CUATM: 0150, SEC.RISCANI
 Activitatea principala: G4646, Comert cu ridicata al produselor farmaceutice
 Forma proprietate: 16, Proprietate colectivă
 Forma organizatorico-juridica: 530, Societăți cu răspundere limitată
 Cod CUIO: 40717392
 Codul fiscal: 1010600028048
 WEB:
 Numele si coordonatele al contabilului-sef: Nasedchin Alexandr
 Telefon: +37322808719
 Numărul mediu scriptic al personalului în perioada precedentă: 6 persoane.

Unitatea de masura: leu

Notă informativă privind veniturile și cheltuielile clasificate după natură

Anexa 8

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	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		
Contributii 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

Anexa 1

Nr. cpt.	ACTIV	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
	Active imobilizate			
	Imobilizari necorporale	010	<u>1137</u>	<u>487</u>
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	<u>938614</u>	<u>2208593</u>
	Resurse minerale	050		
	Active biologice imobilizate	060		
1.	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	<u>939751</u>	<u>2209080</u>
	Active circulante			
	Materiale	140		<u>6209</u>

Nr. cpt.	ACTIV	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160	<u>51520</u>	<u>47842</u>
	Productia in curs de executie si produse	170		
	Marfuri	180	<u>4809995</u>	<u>5710647</u>
	Creante comerciale	190	<u>5528804</u>	<u>4337729</u>
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	<u>2496545</u>	<u>1647170</u>
	Creante ale bugetului	220	<u>26401</u>	<u>166486</u>
	Creante ale personalului	230		
	Alte creante curente	240		
	Numerar in casierie si la conturi curente	250	<u>9066228</u>	<u>8911899</u>
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	<u>3712</u>	<u>742</u>
	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	<u>21983205</u>	<u>20828724</u>
Total active (rd.130 + rd.300)	310	<u>22922956</u>	<u>23037804</u>	
3.	Capital propriu			
	Capital social si suplimentar	320	<u>5400</u>	<u>5400</u>
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340		x
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	<u>18182879</u>	<u>12119049</u>
	Profit net (pierdere neta) al perioadei de gestiune	360		x
	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	<u>18188279</u>	<u>21026865</u>	
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			
5.	Datorii curente			
	Credite bancare pe termen scurt	450		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	<u>3883519</u>	<u>1331928</u>
	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	<u>135390</u>	<u>159545</u>
	Datorii fata de personal	500	<u>152404</u>	<u>2913</u>
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	<u>492060</u>	<u>434590</u>
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	<u>71304</u>	<u>81963</u>
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	<u>4734677</u>	<u>2010939</u>	
Total pasive (rd.390 + rd.440 + rd.580)	590	<u>22922956</u>	<u>23037804</u>	

SITUATIA DE PROFIT SI PIERDERE

de la pina la

Anexa 2

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

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

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

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Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la inceputul perioadei de gestiune	Majorari	Diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6	7
1	Capital social si suplimentar					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	()	()	()	()
	Capital neinregistrat	040				
	Capital retras	050	()	()	()	()
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
2	Rezerve					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
3	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 noile reglementari contabile	150				
	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160				
4	Alte elemente de capital propriu, din care	170				
	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 vinzari	010		
Plati pentru stocuri si servicii procurate	020		
Plati catre angajati si organe de asigurare sociala si medicala	030		
Dobinzi 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		
Dobinzi 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 inceputul perioadei de gestiune	230		
Sold de numerar la sfirsitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Date generale

Anexa 6

1. Certificat de inregistrare a entitatii, eliberat de Camera Inregistrarii de Stat.

Numar de inregistrare Data inregistrarii Seria Numar

2. Capital social inregistrat de Camera Inregistrarii de Stat:

data , suma lei, inclusiv:

1) cota statului lei,

2) cota detinatorilor a cel putin 20% Increase lei.

Modificari ulterioare:

a) , suma lei, inclusiv cota statului lei,

b) , suma lei, inclusiv cota statului lei.

3. 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					

4. Numarul mediu scriptic al personalului in perioada de gestiune 6 persoane, inclusiv pe categorii:

1) personal administrativ 6 persoane,

2) muncitori persoane.

5. Numarul personalului la 31 decembrie 2019 6 persoane.

6. Remunerarea personalului entitatii in perioada de gestiune 326523 lei.

7. Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensiile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.

8. Avansurile si creditele acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.

9. Valoarea activelor imobilizate si circulante, inregistrate in calitate de gaj

1) valoarea de gaj lei,

2) valoarea contabila lei.

10. Numarul actiunilor ordinare la finele perioadei de gestiune unitati.

11. Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:

1) profit lei,

2) pierdere lei.

12. Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:

1) platite lei,

2) planificate pentru plata lei.

13. 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			

14. Numerar legat - total lei.

In rindurile, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:

a) la numator - valoarea de gaj;

b) la numitor - valoarea contabila

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

Tabelul 1

Creante, investitii financiare si datorii pe termen lung 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
			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

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

Tabelul 2

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
---	---	---	---	---	---	---

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

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

Tabelul 3

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	lesiri / 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	10
Creante si investitii financiare curente - total	010								
Creante comerciale, inclusiv pe tari:	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, inclusiv pe tari:	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, inclusiv pe tari:	050								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	060								
Datorii comerciale, inclusiv pe tari:	070								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, inclusiv pe tari:	080								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090								

1	2	3	4	5	6	7	8	9	10
Datorii privind dividendele calculate, inclusiv pe tari:	100								

1	2	3	4	5	6	7	8	9	10
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

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

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	10
Creante si investitii financiare curente - total	010								
Creante comerciale, <i>inclusiv pe tari:</i>	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, <i>inclusiv pe tari:</i>	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, <i>inclusiv pe tari:</i>	040								

1	2	3	4	5	6	7	8	9	10
Depozite, <i>inclusiv pe tari:</i>	050								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, <i>inclusiv pe tari:</i>	060								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	070								
Datorii comerciale, <i>inclusiv pe tari:</i>	080								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, <i>inclusiv pe tari:</i>	090								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, <i>inclusiv pe tari:</i>	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, <i>inclusiv pe tari:</i>	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

Anexa 9

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

Tabelul 5

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, <i>inclusiv pe tari:</i>	020				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, <i>inclusiv pe tari:</i>	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, <i>inclusiv pe tari</i> :	050				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, <i>inclusiv pe tari</i> :	060				

Rd.010= rd.020 + rd.030

Rd.040= rd.050 + rd.060

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

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

Tabelul 6

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 vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe tari</i> :	020		

1	2	3	4
Venituri din dobinzi aferente activitatii operationale si altor activitati, <i>inclusiv pe tari</i> :	030		

1	2	3	4
Venituri din dividende si participatii in alte entitati, <i>inclusiv pe tari</i> :	040		

1	2	3	4
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, <i>inclusiv pe tari</i> :	050		

1	2	3	4
Alte venituri, <i>inclusiv pe tari</i> :	060		

1	2	3	4
Cheltuieli - total	070		
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe tari</i> :	080		

1	2	3	4
Cheltuieli privind dobinzile, <i>inclusiv pe tari</i> :	090		

1	2	3	4
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, <i>inclusiv pe tari</i> :	100		

1	2	3	4
Alte cheltuieli, <i>inclusiv pe tari</i> :	110		

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060

Rd.070= rd.080 + rd.090 + rd.100 + rd.110

Anexa 9

NOTA INFORMATIVA privind relatiile cu nerezidentii

Tabelul 7

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, <i>inclusiv pe tari</i> :	010				

1	2	3	4	5	6
---	---	---	---	---	---

1	2	3	4	5	6
Bunuri primite spre prelucrare, <i>inclusiv pe tari:</i>	020				

1	2	3	4	5	6
Bunuri obtinute din materialele prelucrate, <i>inclusiv pe tari:</i>	030				

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

Informațiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rind	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 sfârșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfârșitul perioadei	Deprecierea acumulată la sfârșitul 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 neînregistrate în bilanț	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)

Biosistem 2019.pdf

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Recipisa

Respondent

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

A prezentat raportul: RSF1

Pentru perioada fiscală: A/2019

Data prezentării: 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

 **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.

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)	Metanephrines
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 (AACCA)	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-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

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
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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

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 2020, 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

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 Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt 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) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos 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 المنجاة المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعلیمة ان شركة دایموند دایاغونوستکس تصرح و تؤكد أن

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

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

Model: Diamond Diagnostics SmartLyte/CareLyte/Gemlyte

Reagent & Controls:

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

Electrodes & Accessories:

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

(AR) Authorized Representative

Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized Officer:

Kathy Fisher
Kathy Fisher
Global Quality Manager

Date: 30 April, 2018

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



This is to certify that the Quality Management System of:

Diamond Diagnostics Inc.

333 Fiske Street
Holliston MA 01746
United States of America

(See appendix for additional locations)

applicable to:

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

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

For and on behalf of NQA, USA



Certificate Number: 16590
EAC Code: 34
Certified Since: November 10, 2005
Valid Until: November 6, 2020
Reissued: November 7, 2017
Cycle Issued: November 7, 2017

Certificate of Registration



global assurance

Appendix to Certificate Number: 16590

Includes Facilities Located at:

Diamond Diagnostics Inc.

Certificate Number 16590
333 Fiske Street
Holliston MA 01746
United States of America

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

Lowland Street

Certificate Number 16590
74 Lowland Street
Holliston MA 01746
United States of America

Warehouse



Certified Since: November 10, 2005

Valid Until: November 6, 2020

Reissued: November 7, 2017

Cycle Issued: November 7, 2017



This is to certify that the Quality Management System of:

Diamond Diagnostics Inc.

333 Fiske Street
Holliston MA 01746
United States of America

Central function listed above. See appendix for additional locations

applicable to:

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

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016



K M Beard

For and on behalf of NQA, USA

Certificate Number: 17163
EAC Code: 34
Certified Since: February 7, 2006
Valid Until: November 6, 2020
Reissued: November 7, 2017
Cycle Issued: November 7, 2017



Certificate of Registration



global assurance

Appendix to Certificate Number: 17163

Includes Facilities Located at:

Diamond Diagnostics Inc.

Certificate Number 17163
333 Fiske Street
Holliston MA 01746
United States of America

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

Lowland Street

Certificate Number 17163
74 Lowland Street
Holliston MA 01746
United States of America

Warehouse



Certified Since: February 7, 2006

Valid Until: November 6, 2020

Reissued: November 7, 2017

Cycle Issued: November 7, 2017

Declaration of Conformity



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

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

Product: Auto Hematology Analyzer

Model: BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26

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

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity



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

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

AMZ MEDICAL

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 Immunoassay 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

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



(Dawn M. Tibodeau)
Manager, Certification Body MHS

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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

Page 4 of 4

Date of Issue: 2019-11-25



(Dawn M. Tibodeau)
Manager, Certification Body MHS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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 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

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