



REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul
(adresa juridică) a titularului de licență

Societatea cu Răspundere Limitată
"BIOSISTEM MLD"

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de
înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare
a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial,
pentru a cărui desfășurare se eliberează licența

* Importul, comercializarea, asistența tehnică
și reparația dispozitivelor medicale *

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1) 19.10.2012; 2) 14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

Semnătura conducătorului
autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL

(Denumirea completă)

407173921010600028048

(Cod CUIIO)(Cod IDNO)

Sediul: MD MD-2001MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.RÎȘCANI150

(Cod poștal)Raionul (municipiul, UTA); LocalitateaCod CUATM

Albisoara, 16, 1, of.7

Activitatea principală: strada, nr, bl. Comert cu ridicata al produselor farmaceutice

G4646

Cod CAEM, rev.2

Forma de proprietate: Proprietate privată15

Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA530

Cod CFOJ

Date de contact: Tel. +37322808719 e-mail biosistem.mld@gmail.com

WEB:

Numele și coordonatele al contabilului-șef: Dl (dna) +37322808719

Unitatea de măsură: leu

Tel. +37369463619

Anexa 8

Notă informativă privind veniturile și cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Alte venituri din activitatea operațională	020		500
Venituri din alte activități	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variația stocurilor	050		
Costul vânzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	35.709	46.530
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activități	120	289.432	558.776
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	11.036.312	12.904.326
Profit (pierdere) până la impozitare (rd.040 – rd.130)	140	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	150	595.238	959.194
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	4.361.102	6.996.028

BILANȚUL

Anexa 1

la 31.12.2017				
Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiții financiare pe termen lung în părți neafiliate	070		
	Investiții financiare pe termen lung în părți afiliate	080		
	Investiții imobiliare	090		
	Creanțe 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	197.962	906.490
2.	Active circulante			
	Materiale	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160	49.454	63.968
	Producția în curs de execuție și produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanțe comerciale	190	5.303.786	3.157.174
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanțe ale bugetului	220	35.037	4.973
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	8.004	5.373
	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	10.375.896	13.501.563
	Total active (rd.130 + rd.300)	310	10.573.858	14.408.053

Nr. crt.	PASIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
3.	Capital propriu			
	Capital social și suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecții ale rezultatelor anilor precedenți	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	350	8.952.137	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	360	X	6.996.028
	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	8.957.537	12.645.055
4.	Datorii pe termen lung			
	Credite bancare pe termen lung	400		
	Împrumuturi 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		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.084.518	1.595.609
	Datorii față de părțile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii față de personal	500	7.343	45.149
	Datorii privind asigurările sociale și medicale	510		
	Datorii față de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii față de proprietari	540		
	Finanțări și încasări cu destinație specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	19.762	75.239
	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	1.616.321	1.762.998
	Total pasive (rd.390 + rd.440 + rd.580)	590	10.573.858	14.408.053

SITUAȚIA DE PROFIT ȘI PIERDERE

Anexa 2

de la 01.01.2017 până la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Costul vânzărilor	020	9.960.221	11.372.168
Profit brut (pierdere brută) (rd.010 – rd.020)	030	5.663.488	9.125.008
Alte venituri din activitatea operațională	040		500
Cheltuieli de distribuție	050	208	202
Cheltuieli administrative	060	513.937	622.704
Alte cheltuieli din activitatea operațională	070	272.514	350.476
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	4.876.829	8.152.126
Rezultatul din alte activități: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) până la impozitare (rd.080 + rd.090)	100	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	110	595.238	959.194
Profit net (pierdere netă) al perioadei de gestiune (rd.100 – rd.110)	120	4.361.102	6.996.028

SITUAȚIA MODIFICĂRIILOR CAPITALULUI PROPRIU

Anexa 3

de la 01.01.2017 până la 31.12.2017

Nr. 3/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
1	Capital social și suplimentar					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevârsat	030	0	0	0	0
	Capital netregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social și suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2	Rezerve					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
3	Profit nerepartizat (pierdere neacoperită)					
	Corecții ale rezultatelor anilor precedenți	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	5.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziția la noile reglementări contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	8.952.137	11.357.131	7.669.613	12.639.655
4	Alte elemente de capital propriu, din care					
	Diferențe din reevaluare	171				
	Subvenții entităților cu proprietate publică	172				

Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	8.957.537	11.357.131	7.669.613	12.645.055
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SITUAȚIA FLUXURILOR DE NUMERAR

Anexa 4

de la 01.01.2017 până la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010	16.364.220	30.547.593
Plăți pentru stocuri și servicii procurate	020	18.057.882	1.242.716
Plăți către angajați și organe de asigurare socială și medicală	030	165.559	205.235
Dobânzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăți	070	647.102	20.861.222
Fluxul net de numerar din activitatea operațională (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080	-692.095	7.024.700
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 – rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200	-1.127.660	-3.110.000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1.819.755	3.914.700
Diferențe de curs valutar favorabile (nefavorabile)	220	79.511	79.511
Sold de numerar la începutul perioadei de gestiune	230	2.488.073	747.829
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Date generale

1. Certificat de înregistrare a entității, eliberat de Camera Întreprinderi de Stat:
 Număr de înregistrare MD010250, Data înregistrării 12.08.2014, Seria MD, Număr 010250
2. Capital social înregistrat de Camera Întreprinderi de Stat:
 data 12.08.2010, suma 5.400 lei, inclusiv:
 1) cota statului _____ lei,
 2) cota deținătorilor a cel puțin 20% _____ lei,
 Modificări ulterioare:
 a) _____ suma _____ lei, inclusiv cota statului _____ lei,
 b) _____ suma _____ lei, inclusiv cota statului _____ lei.
3. Entitățile, activitatea cărora necesită licență, indică:
 Licența în vigoare:
 1) Număr 044322, data eliberării 2010-10-04 00:00:00
 Termen de valabilitate 03.10.2020
 Tipul de activitate _____
 Organul care a eliberat licența _____
4. Numărul mediu scriptic al personalului în perioada de gestiune _____ persoane, inclusiv pe categorii:
 1) personal administrativ _____ persoane,
 2) muncitori _____ persoane.
5. Numărul personalului la 31.12.2017 _____ persoane.
6. Remunerarea personalului entității în perioada de gestiune _____ lei.
7. Remunerarea membrilor organelor de administrare, de conducere și supraveghere și alte angajamente apărute sau asumate în legătură cu pensile membrilor actuali sau ale foștilor membri ai acestor organe, pe categorii _____ lei.
8. Avansurile și creditele acordate membrilor organelor specificate la pct.7 _____ lei, inclusiv rambursate _____ lei.
9. Valoarea activelor imobilizate și circulante, înregistrate în calitate de ga¹
 1) valoarea de ga¹ _____ lei,
 2) valoarea contabilă _____ lei.
10. Numărul acțiunilor ordinare la finele perioadei de gestiune _____ unități.
11. Profit net (pierdere netă) a perioadei de gestiune pentru o acțiune ordinară:
 1) profit _____ lei,
 2) pierdere _____ lei.
12. Dividende calculate pentru o acțiune ordinară pentru perioada de gestiune:
 1) plătite _____ lei,
 2) planificate pentru plată _____ lei.
13. Valută standard disponibilă, calculată în moneda națională a Republicii Moldova – total 849.462 lei,
 inclusiv (lei, denumirea și codul valutei):
 1) 698537 _____ codul valutei Euro
 2) 150925 _____ codul valutei US Dollar

14. Numerar legat – total _____ lei

În rîndurile, în care se înscriu sumele de gaj, în toate coloanele prin fracție se reflectă:

b) la numitor – valoarea contabilă

Informatiile privind activele imobilizate

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Nr. rând	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
		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200	3.25f	81.3				3.25f	1.463	
2.1 brevete și mărci	210								
2.2 licențe de activitate	220		81.3				3.25f	1.463	
2.3 programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		X					X	
5. Milioane fixe, total din care:	500	205.204f	9.679		796.422	6.100	995.526	98.823	
5.1 clădiri	510								
5.2 construcții speciale	520								
5.3 mașini, utilaje, instalații de transmisie	530	186.815	8.340		796.422	6.100	971.141	83.529	
inclusiv: tehnica de calcul	531								
5.4 mijloace de transport	540								
5.5 instrumente și inventar	550								
5.6 costuri ulterioare aferente obiectelor neintegrare 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		1.379				18.385	6.894	
6. Resurse minerale	600								
7. Investiții mobiliare, total	700								

Recipisa de primire a raportului

ID-ul raportului	289272
Tipul raportului	RSF1
Tipul perioadei de raportare	Annual
Anul de raportare	2017
Numărul de raportare a perioadei (număr)	10
Numărul de raportare a perioadei (text)	an
Codul statistic al organizației	40717392
Codul fiscal al organizației	1010600028048
IDNO organizației	1010600028048
Denumirea organizației	BIOSISTEM MLD SRL
Statutul raportului	Primit la BNS
Data creării raportului	26.03.2018 11:08:42
Data expedierii raportului	27.03.2018 13:54:13
Subdiviziunea teritorială a BNS	mun. Chișinău
Telefonul subdiviziunii teritoriale a BNS	0-22-739581

Таблицы финансового отчёта автоматически проверены на арифметические ошибки и логические связи между таблицами.

Контроль показателей на соответствие с предыдущим финансовым отчётом на данный момент НЕ выполнен.

Ответственность за правильность отражения экономических операций в бухгалтерском учёте и применённых методов учёта, а также за достоверность и полноту представленных данных и приложений несёт субъект и его ответственные лица, подписавшие финансовые отчёты.

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ A1910795

din
от 12.03.2019

1. Destinatar / Получатель

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 Автоматизированной Информационной Системы

La data emiterii prezentului certificat restanța la 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 27.03.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef. Serv. Riscani
Funcția/Dолжность
L.S./ М.П.
Executor: *[Signature]*
Numele și prenumele/Фамилия и имя

Ana Hrisov
Numele și prenumele/Фамилия и имя



Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 12.03.2019 ora 10:26:54
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,33)

ORDIN DE PLATA		nr.	86	DATA EMITERII	14 03 2019	TIP.DOC. 1
PLATITI	8000.00	LEI	Opt Mii lei 00 bani			
PLATITOR	(R) "BIOSISTEM MLD" S.R.L.		Cod IBAN	MD95ML000000002251429243		
			CODUL FISCAL	1010600028048		
PRESTATORUL PLATITOR	suc. "Invest"			CODUL BANCII	MOLDMD2X329	
BENEFICIAR	(R) IMSP Centrul de Sanatate Nr.1 Orhei		Cod IBAN	MD24ML000000002251033306		
			CODUL FISCAL	1013606002553		
PRESTATORUL BENEFICIAR	suc. Orhei			CODUL BANCII	MOLDMD2X333	
DESTINATIA PLATII	Pentru garantia pentru oferta la licitatie publica nr. ocds-b3wdp1-MD-1550478458258 din 15 mart 2019			TIPUL TRANSFERULUI NORMAL/URGENT N L.S. SEMNATURILE EMITENTULUI		
CODUL TRANZACTIEI	DATA PRIMIRII	DATA EXECUTARII				
001	14 03 2019	14 03 2019 15:52:58				
			SEMNATURA PRESTATORULUI			



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

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

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



Xavier Palomar
Area Manager
27-April-2011



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

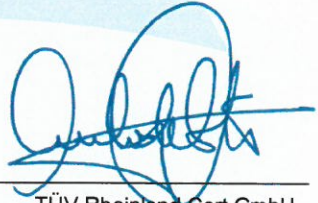
(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:
- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.
Distribution and servicing of instruments and reagents 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 2017-12-13 until 2019-12-18.
First certification 1996

2017-12-14


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

No.	Location	Scope
/01	BIOSYSTEMS, S.A. Pl. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labelling and assembling of reagents. Warehousing and shipment of: -Instruments and Reagents for clinical diagnostic. -Instruments and Reagents for agro-alimentary analysis. -Instruments and Reagents for veterinary diagnosis.

2017-12-14



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

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: 2017-11-28
Certificate Registration No.: SX 60124804 0001
An audit was performed. Report No.: 28300434 002
This Certificate is valid until: 2019-12-12

Certification Body



Date 2017-11-28



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

**Attachment to
Certificate**

Registration No.: SX 60124804 0001
Report No.: 28300434 002

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

Scope:

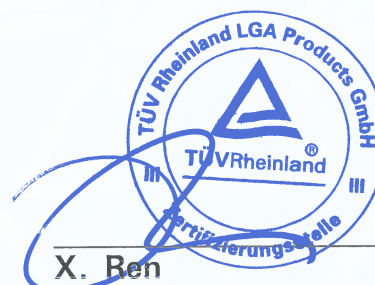
Site included:
Polígono Industrial "Can Tapioles"
Naves 7, 12 y 13
08110 Montcada i Reixac (Barcelona)
Spain

Scope:
Labelling and Assembling of reagents and
Warehousing and Shipment of instruments and
reagents for clinical diagnostic

Certification Body



Date: 2017-11-28



Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.



Сертификат

Poiate Vitalie

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Центр поддержки клиентов Mindray Medical Russia Ltd.



Дата: 09 октября 2015 года



Product Service

CERTIFICATE

No. Q5 17 03 44751 089

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA



Certification Mark:



Scope of Certificate: Design and development, production and distribution of Active medical devices (intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro diagnostic instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits (intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1705528

Valid from: 2017-09-01

Valid until: 2020-08-31

Date, 2017-06-28

Stefan Preiß



Page 1 of 3





Product Service

CERTIFICATE**No. Q5 17 03 44751 089****Applied Standard(s):**

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

Facility(ies):

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

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park,
Baimang, Xili Town, Nanshan, 518108 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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



Product Service

Attachment for Certificate No. Q5 17 03 44751 089
Dated: 2017-06-28

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

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder,
 Anesthesia Machine and Accessories, Ventilator,
 Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
 Ultrasonic Diagnostic Equipment and Accessories,
 Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
 Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
 Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay Analyzer,
 Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer,
 Glycohemoglobin Analyzer, Specific Protein Analyzer,
 Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer,
 Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav 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

Munich, CRT, 2017-06-28

Stefan Preiß

Page 3 of 3

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

AWAYDOR



America

CERTIFICATE

No. QS5 17 07 44751 097

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:

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, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

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.:

M2606

Effective Date:

2017-07-01

Expiry Date:

2020-06-30

Earl Buckmiller

Director, Quality Systems & MS Cert. Body



Page 1 of 3

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

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, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park
Baimang, Xili Town
Nanshan, 518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Manufacturing of 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, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: 2017-07-01
 Expiry Date: 2020-06-30

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 2 of 3

TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue
Guangming District
518016 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories (Ultrasonic Transducer), Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: 2017-07-01
Expiry Date: 2020-06-30

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 3 of 3

TÜV SÜD America Inc.
 10 Centennial Drive
 Peabody, MA 01960
 USA

TÜV®



21.08.2016
İzmir / Turkey

DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

FOR ANNEX II LIST A which includes HIV, Hepatitis B and Hepatitis C tests; the Notified Body must verify that the product meets the Common Technical Specification (CTS) and must release each batch of product before it is placed on the European market. The batch release often requires testing. These have EC Design Examination certificates by the notified body.

FOR ANNEX III which includes all other tests for Professional use; the manufacturer prepares a declaration of conformity in a similar way to the general devices.

For the above mentioned reason, we hereby declare that we provide CE Certificate for only the Hepatitis B, Hepatitis C and HIV tests for Professional use. For the group of other Professional tests; it is enough to present a self-Declaration of Conformity to the EU standards.

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

HBsAg Test

Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜKLAB Tıbbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
İzmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

Application No. 45/2016
Contract No. MD-18/2016

Module H6



EC CERTIFICATE No. 1434-IVDD-57/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. 4, 6 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law. The audit of the quality
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 45/2016
Contract No. MD-18/2016

Module H7



EC CERTIFICATE No. 1434-IVDD-52/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical
device, List A:

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law and comply with the
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 43/2016
Contract No. MD-16/2016

Module H6



EC CERTIFICATE No. 1434-IVDD-53/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law. The audit of the quality
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 43/2016
Contract No. MD-16/2016

Module H7



EC CERTIFICATE No. 1434-IVDD-54/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical
device, List A:

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law and comply with the
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 44/2016
Contract No. MD-17/2016

Module H6



EC CERTIFICATE No. 1434-IVDD-55/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law. The audit of the quality
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 44/2016
Contract No. MD-17/2016

Module H7



EC CERTIFICATE No. 1434-IVDD-58/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical
device, List A:

Anti - HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law and comply with the
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 46/2016
Contract No. MD-19/2016

Module H6



EC CERTIFICATE No. 1434-IVDD-59/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

Anti - HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law. The audit of the quality
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 46/2016
Contract No. MD-19/2016

Module I17



EC CERTIFICATE No. 1434-IVDD-51/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical
device for self-testing:

hCG Pregnancy Test
Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Labmen®
Tester®, Rapidan Compact®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex III p. 6 Directive 98/79/EC
(with subsequent amendments) transposed into the Polish law and comply with the
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



Anna Wyroba
Anna Wyroba
Vice President of PCBC

PCBC Notified Body
23A, Kłobucka Str., PL-02-699 Warsaw

CE 1434

Application No. 42/2016
Contract No. MD-15/2016

Module A1



CERTIFICATE

No. J - 2670/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.

**Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5
35621 Çiğli, İzmir, Turkey**

Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro diagnostic medical devices
intended for self-testing and professional use,
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019
QMS



Anna Wyroba, M.Sc.
Vice President



Certificate No. **J - 2670/2/2018**

Issued under the Contract No. 2897/JM/3/2017

Date of certification decision: 24.08.2018

Bears the PCBC hologram.

Warsaw, 24.08.2018



CERTIFICATE

No. M - 56/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.
Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5
35621 Çiğli, İzmir, Turkey
Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro diagnostic medical devices
intended for self-testing and professional use,
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019
QMS



Anna Wyroba
Anna Wyroba, M.Sc.
Vice President



Certificate No. **M-56/2/2018**

Issued under the Contract No. 2897/JM/3/2017

Date of certification decision: 24.08.2018

Bears the PCBC hologram.

Warsaw, 24.08.2018