



# 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**

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

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2100120**

din  
от **05.01.2021**

**1. Destinația / Назначение**

Pentru participare la proceduri de achiziții publice

**2. Date despre contribuabil / Информация о налогоплательщике**

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

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

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

**4. Valabil pînă la / Действителен до 20.01.2021**

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

**Șef DDF Rîșcani**

Funcția/Doljnost  
**a DGAF mun.Chișinău**

L.Ș/ М.П.

Executiv  
**Svetlana Slonovscaia**  
Numele și prenumele/Фамилия и имя



**Viorica CĂUȘ**

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 05.01.2021 ora 12:23:46  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,42)

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		
<b>Total venituri</b> (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		
<b>Total cheltuieli</b> (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
	<b>Active imobilizate</b>			
	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		
	<b>Total active imobilizate</b> (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>
	<b>Active circulante</b>			
	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>
	<b>Total active circulante</b> (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>
<b>Total active</b> (rd.130 + rd.300)	310	<u>22922956</u>	<u>23037804</u>	
3.	<b>Capital propriu</b>			
	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		
<b>Total capital propriu</b> (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	<u>18188279</u>	<u>21026865</u>	
4.	<b>Datorii pe termen lung</b>			
	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		
<b>Total datorii pe termen lung</b> (rd.400 + rd.410 + rd.420 + rd.430)	440			
5.	<b>Datorii curente</b>			
	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>
	<b>Total datorii curente</b> (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>
<b>Total pasive</b> (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

de la pina la

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	<b>Capital social si suplimentar</b>					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	()	()	()	()
	Capital neinregistrat	040				
	Capital retras	050	()	()	()	()
	<b>Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)</b>	060				
2	<b>Rezerve</b>					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	<b>Total rezerve (rd.070 + rd.080 + rd.090)</b>	100				
3	<b>Profit nerepartizat (pierdere neacoperita)</b>					
	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				
	<b>Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)</b>	160				
4	<b>Alte elemente de capital propriu, din care</b>	170				
	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	<b>Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)</b>	180				

## SITUATIA FLUXURILOR DE NUMERAR

de la pina la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
<b>Fluxuri de numerar din activitatea operationala</b>			
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		
<b>Fluxul net de numerar din activitatea operationala (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070 )</b>	080		
<b>Fluxuri de numerar din activitatea de investitii</b>			
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
<b>Fluxul net de numerar din activitatea de investitii</b> (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
<b>Fluxuri de numerar din activitatea financiara</b>			
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		
<b>Fluxul net de numerar din activitatea financiara</b> (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
<b>Fluxul net de numerar total</b> (± rd.080 ± rd.140 ± rd.200)	210		
Diferente de curs valutar favorabile (nefavorabile)	220		
<b>Sold de numerar la inceputul perioadei de gestiune</b>	230		
<b>Sold de numerar la sfirsitul perioadei de gestiune</b> (± 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 numarator - 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
<b>Creante si investitii financiare pe termen lung - total</b>	010					
Creante comerciale, <i>inclusiv pe tari:</i>	020					

1	2	3	4	5	6	7
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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
<b>Datorii pe termen lung - total</b>	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
<b>Creante si investitii financiare pe termen lung - total</b>	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
<b>Datorii pe termen lung - total</b>	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
<b>Creante si investitii financiare curente - total</b>	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
<b>Datorii curente - total</b>	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
<b>Creante si investitii financiare curente - total</b>	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
<b>Datorii curente - total</b>	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
<b>Investitii financiare</b>	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
<b>Capital social</b>	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
<b>Venituri - total</b>	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
<b>Cheltuieli - total</b>	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

 **Versiune de imprimare** **Salvare**

## 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 6<sup>th</sup>, 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	
Biochemistry Control Serum (Human) I	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) II	Hemoglobin A2 Control
Biochemistry Control Serum I	Lipid Control Serum I
Biochemistry Control Serum II	Lipid Control Serum II
CK-MB Control Serum	Protein Control Serum I
Control Urine	Protein Control Serum II
Fertility Biochemistry Control	Rheumatoid Control Serum I
Hemoglobin A1C Control (Elevated)	Rheumatoid Control Serum II

## **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  
Am Grauen Stein · 51105 Köln

Page 1 of 1

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# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**BIOSYSTEMS S.A.**  
**Costa Brava 30**  
**08030 Barcelona**  
**Spain**

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

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

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

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

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

Certification Body



Date 2020-01-08



D. Swiatko

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

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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

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

**Scope:**

Site included:

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

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

**Certification Body**



**Date: 2020-01-08**

**D. Swiatko**



# Declaration of Conformity



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

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

**Authorized Representative:** Emergo Europe

Molenstraat 15 2513 BH The Hague  
The Netherlands

**Medical Device :** Product Name: Reagent strips for Urinalysis

IVDD-Classification: Professional use

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

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

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

**This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.**

Valid Since  
May 9<sup>th</sup>, 2012  
Changchun, China

Representative:  
Yu Ge  
Dirui Industrial Co., Ltd.  
  


(place and date of issue)

(name and signature or equivalent marking of authorized person)

# 认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306**


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

认证范围：**体外诊断医疗器械的设计开发、生产和销售**

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期：**证书有效期从 2018-05-03 至 2021-05-02。**  
此证书须经过符合要求的监督审核保持有效。

2018-05-03

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 9001:2015**

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

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

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

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

Validity: **The certificate is valid from 2018-05-03 until 2021-05-02.  
It remains valid subject to satisfactory surveillance audits.**

2018-05-03



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Dirui Industrial Co., Ltd.**  
**95 Yunhe Street**  
**New & High Tech.**  
**Development Zone**  
**Changchun**  
**Jilin Province 130012**  
**China**

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

**Design and Development, Manufacture and Distribution of  
In vitro Diagnostic Medical Test Systems  
(see attachment for products and additional site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

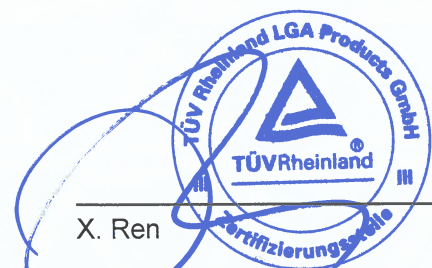
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-26  
Certificate Registration No.: SX 60127937 0001  
An audit was performed. Report No.: 15047317 007  
This Certificate is valid until: 2020-03-01

Certification Body



Date 2018-06-26



**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 60127937 0001  
**Report No.:** 15047317 007

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

**Scope:**

**Products:**

- Urine Test Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Immunochemistry Test Systems (Reagents, Analyzers, Controls)
- Vaginal Infections Test Systems (Reagents, Analyzers, Controls)

**Site included:**

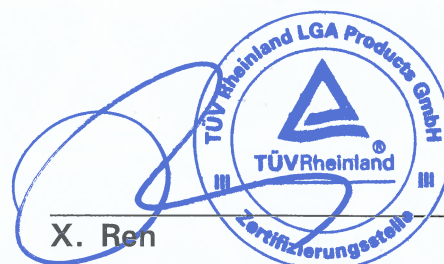
3333 Yiju Street, New & High Tech. Development Zone,  
Changchun, 130103 Jilin, China

Design and Development, Manufacture and Distribution of  
Urine Test Analyzers, Hematology Test Analyzers, Clinical  
Chemistry Test Analyzers, Immunochemistry Test Analyzers,  
Vaginal Infections Test Analyzers

**Certification Body**



**Date:** 2018-06-26



# Declaration of Conformity **CE**

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

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

**Product:** Auto Hematology Analyzer  
**Model:** BC-3600

Including reagents as following:

**M-30D DILUENT**  
**M-30CFL LYSE**  
**M-30R RINSE**  
**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:** 2011-01-14

**Place, Date of Issue:** Shenzhen, 2011-01-14

**Signature:** \_\_\_\_\_

**Name of Authorized Signatory:** Mr. Yang Long

**Position Held in Company:** Management Representative





America

# CERTIFICATE

No. QS6 044751 0135 Rev. 01

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

**Certification Mark:**



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

**Standard(s):** ISO 13485:2016

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

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

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

**DUNS No:** 65-467-1304

**Effective Date:** 2019-08-26

**Expiry Date:** 2021-10-23

Page 1 of 4

**Date of Issue:** 2019-11-25

( Dawn M. Tibodeau )  
 Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)



# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Regulatory Requirements:    Audit/Certification Criteria**

**Australia**

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

**Brazil**

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

**Canada**

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

**United States**

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

**Japan**

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

**Overall Scope Statement:**

**Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence 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

Page 3 of 4

Date of Issue: 2019-11-25



( Dawn M. Tibodeau )  
Manager, Certification Body MHS





America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

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

**Certification Mark:**



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

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

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

**Report No.:** SH2005501

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

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

Page 1 of 4

**Date of Issue:** 2020-08-20

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



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

## Overall Scope Statement

**Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence 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



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:

**TÜRKLAB 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*  
**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*  
**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*  
**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*  
**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

**CE 1434**  
PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

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

Module H7



**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®, Rapidan  
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

**CE 1434**  
PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

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