

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

din
от

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

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

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /

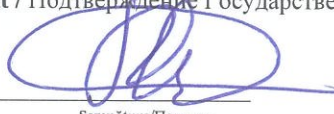
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

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

4. Valabil pînă la / Действителен до 19.01.2022

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





Semnătura/Подпись

Petru GRICIUC

Numele și prenumele/Фамилия и имя

L.S/ M.П.

Executor:

Claudia GOJAN
Numele și prenumele/Фамилия и имя
Tel.(022)323102

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 04.01.2022 ora 14:01:02
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)



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: MOLDM2X329

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: MOLDM2X329

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 MOLDM2X329.

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





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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.**

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,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

Cod Fiscal: 1010600028048; IBAN: MD95ML00000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Scrisoare de informare

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



Vitalie Poiata

L.Ș.

Data predăstării 11.05.2021 10:00:47

Anexa la SNC
"Prezentarea situațiilor financiare"
Aprobat de Ministerul Finanțelor
al Republicii Moldova

SITUAȚIILE FINANCIARE
pentru perioada 01.01.2020 - 31.12.2020

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIU: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DOF RISCANI
Cod CUATM: 0150, SEC RISCANI
Strada: SECTORUL RISCANI STR Albisoara nr.16 bl.1 of.7

Activitatea principală: 28669, Comerț cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societate cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:

E-mail: zml13@mail.ru
Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
A C T I V				
ACTIVE IMOBILIZATE				
I. Imobilizări necorporale				
1.	Imobilizări necorporale în curs de execuție	010		
2.	Imobilizări necorporale în exploatare, total	020	487	
din care:				
2.1.	concesiunile, licențe și mărci	021	487	
2.2.	drepturi de autor și titluri de protecție	022		
2.3.	programe informatice	023		
2.4.	alte imobilizări necorporale	024		
3.	Fond comercial	030		
4.	Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	487	
II. Imobilizări corporale				
1.	Imobilizări corporale în curs de execuție	060		
2.	Terenuri	070		
3.	Mijloace fixe, total	080	2208593	2793637
din care:				
3.1.	căldiri	081		
3.2.	construcții speciale	082		
3.3.	mașini, utilaje și instalații tehnice	083	2204135	2791637
3.4.	mijloace de transport	084		

A.	3.5. inventar și mobilier	085			
	3.6. alte mijloace fixe	086	4458	2000	
	4. Resurse minerale	090			
	5. Active biologice imobilizate	100			
	6. Investiții imobiliare	110			
	7. Avansuri acordate pentru imobilizări corporale	120			
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2208593	2793637	
	III. Investiții financiare pe termen lung				
	1. Investiții financiare pe termen lung în părți nefiliate	140			
	2. Investiții financiare pe termen lung în părți afiliate, total	150			
din care:					
2.1. acțiuni și cote de participație deținute în părțile afiliate	151				
2.2. împrumuturi acordate părților afiliate	152				
2.3. împrumuturi acordate aferente intereselor de participație	153				
2.4. alte investiții financiare	154				
Total investiții financiare pe termen lung (rd.140 + rd.150)	160				
IV. Creațe pe termen lung și alte active imobilizate					
1. Creațe comerciale pe termen lung	170				
2. Creațe ale părților afiliate pe termen lung	180				
Inclusiv: creațe aferente intereselor de participație	181				
3. Alte creațe pe termen lung	190				
4. Cheltuieli anticipate pe termen lung	200				
5. Alte active imobilizate	210				
Total creațe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220				
TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2209080	2793637		
ACTIVE CIRCULANTE					
I. Stocuri					
1.	Materiale și obiecte de mică valoare și scurtă durată	240	54051	51978	
2.	Active biologice circulante	250			
3.	Producția în curs de execuție	260			
4.	Produse și mărfuri	270	5710647	7221203	
5.	Avansuri acordate pentru stocuri	280			
Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	5764698	7273181		
II. Creațe curente și alte active circulante					
1.	Creațe comerciale curente	300	4337729	3912218	
2.	Creațe ale părților afiliate curente	310			
Inclusiv: creațe aferente intereselor de participație	311				
3.	Creațe ale bugetului	320	166486	74631	
4.	Creațele ale personalului	330			
5.	Alte creațe curente	340			
6.	Cheltuieli anticipate curente	350	4	2	
7.	Alte active circulante	360	1647908	5756117	
Total creațe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6152127	9742968		
III. Investiții financiare curente					
1.	Investiții financiare curente în părți nefiliate	380			
2.	Investiții financiare curente în părți afiliate, total	390			
din care:					
2.1.	acțiuni și cote de participație deținute în părțile afiliate	391			
2.2.	împrumuturi acordate părților afiliate	392			
2.3.	împrumuturi acordate aferente intereselor de participație	393			

C.	2.4. alte investiții financiare în părți afiliate	394			
	Total investiții financiare curente (rd.380 + rd.390)	400			
	IV. Numerar și documente bănești	410	8911899	3942779	
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20828724	20958928	
	TOTAL ACTIVE (rd.230 + rd.420)	430	23037804	23752565	
	P A S I V				
	CAPITAL PROPRIU				
	I. Capital social și neînregistrat				
	1.	Capital social	440	5400	5400
	2.	Capital nevărsat	450	()	()
3.	Capital neînregistrat	460			
4.	Capital retras	470	()	()	
5.	Patrimoniul primit de la stat cu drept de proprietate	480			
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400	
II. Prime de capital					
III. Rezerve					
1.	Capital de rezervă	510			
2.	Rezerve statutare	520			
3.	Alte rezerve	530			
	Total rezerve (rd.510 + rd.520 + rd.530)	540			
IV. Profit (pierdere)					
1.	Corecții ale rezultatelor anilor precedenți	550	X		
2.	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	21021465	12085295	
3.	Profit net (pierdere netă) al perioadei de gestiune	570	X	7974831	
4.	Profit utilizat al perioadei de gestiune	580	X	()	
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	21021465	20060126	
V. Rezerve din reevaluare					
VI. Alte elemente de capital propriu					
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	21026865	20065526	
DATORII PE TERMEN LUNG					
1.	Credite bancare pe termen lung	630			
2.	Împrumuturi pe termen lung	640			
din care:					
2.1.	Împrumuturi din emisiunea de obligațiuni	641			
Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642				
2.2.	alte împrumuturi pe termen lung	643			
3.	Datorii comerciale pe termen lung	650			
4.	Datorii față de părțile afiliate pe termen lung	660			
Inclusiv: datorii aferente intereselor de participație	661				
5.	Avansuri primite pe termen lung	670			
6.	Venituri anticipate pe termen lung	680			
7.	Alte datorii pe termen lung	690			
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700			
DATORII CURENTE					
1.	Credite bancare pe termen scurt	710			
2.	Împrumuturi pe termen scurt, total	720			

E.	din care:	721			
	2.1. împrumuturi din emisiunea de obligațiuni	722			
	Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	723			
	2.2. alte împrumuturi pe termen scurt	730	1331928	3252667	
	3.	Datorii comerciale curente	740		
	4.	Datorii față de părțile afiliate curente	741		
	Inclusiv: datorii aferente intereselor de participație	745	159545	188105	
	5.	Avansuri primite curente	760	2913	50
	7.	Datorii privind asigurările sociale și medicale	770		
	8.	Datorii față de buget	780	434590	187676
9.	Datorii față de proprietari	790			
10.	Venituri anticipate curente	800			
11.	Alte datorii curente	810	81963	58541	
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2010939	3687039	
PROVIZIOANE					
1.	Provizioane pentru beneficiile angajaților	830			
2.	Provizioane pentru garanții acordate cumpărătorilor/clientilor	840			
3.	Provizioane pentru impozite	850			
4.	Alte provizioane	860			
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870			
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23037804	23752565	

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pină la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	27319617	25963175
din care:			
venituri din vânzarea produselor și mărfurilor	011	26856566	25044358
venituri din prestarea serviciilor și executarea lucrărilor	012	463051	918817
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		
Costul vânzării, total	020	15672962	15186814
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15672962	15186814
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzării	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuție	050	16306	19740
Cheltuieli administrative	060	964136	1259776
Alte cheltuieli din activitatea operațională	070	417394	640169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10277405	9104279

Venituri financiare, total	090	490609	519239
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093		25612
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	490609	493627
Cheltuieli financiare, total	100	686605	597528
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	686605	597528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-195996	-78289
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-195996	-78289
Profit (pierdere) până la impozitare (rd.080 + rd.150)	160	10081409	9025990
Cheltuieli privind impozitul pe venit	170	1178993	1051159
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	8902416	7974831

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU
de la până la

Anexa 3

Nr. d/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
	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
I.	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
	Rezerve					
	1. Capital de rezervă	080				
III.	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR
de la până la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobânzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite rezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати
Сохранить

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчет: RSE1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчета зарегистрированного в Информационной Системе НБС : 11.05.2021 12:26:31

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

Версия для печати
Сохранить

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчет: RSE1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчета зарегистрированного в Системе Электронной Отчетности и отправленного в Информационную Систему БНС : 11.05.2021 10:00:47

Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARAȚIA 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)	Metanephrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (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-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

BIOSYSTEMS



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

Mr. Nasedchin Alexandr

successfully participated in the service engineer's training
"Random Access Biochemistry Analyzer A15, A25"

May 18-22, Moscow 2009

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

Sergey Vasiliyev



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

www.tuv.com

www.tuv.com



 **TÜVRheinland®**
Precisely Right.

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



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Page 1 of 1

Klicken Sie hier, um Text einzugeben.

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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 H12-800MA | DIRUI H10-800 |
| DIRUI H13-Cr | DIRUI H14-Ca | |
| DIRUI H13-Cr (H-800) | DIRUI H14-Ca (H-800) | |

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

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

Valid Since

May 9th, 2012
Changchun, China

Representative:

Yu Ge

Dirui Industrial Co., Ltd. 睿睿达瑞医疗科技

于歌 股份有限公司



(place and date of issue)

(name and signature or equivalent marking of authorized person)

证书附件

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

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

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

页 1 / 1

认证证书

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

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

所包括场地已列于证书附件上

认证范围：**体外诊断医疗器械的设计开发、生产和销售**

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

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

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/01**

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

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

认证范围: 体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。

此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/02**

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

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

认证范围: 体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。

此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

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

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

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

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

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

including the locations according to annex

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

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

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

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

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

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

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

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

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

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

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

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

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

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

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

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

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

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2101045-1

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

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers and In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

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

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



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

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

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

The scope of certification also covers the following:

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

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



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

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

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

The scope of certification also covers the following:

/02 c/o Dirui Industrial Co., Ltd.
3333 Yiju Street, New & High Tech.
Development Zone, Changchun,
130103 Jilin, P.R. China

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers for Clinical Laboratory Use.

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



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

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.

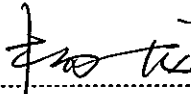
Standards Applied:

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. 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



Certificate

No. Q5 044751 0164 Rev. 02

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

Patient Monitor and Accessories, Vital Signs Monitor,
 Center Monitoring System, Telemetry Monitoring System,
 Pulse Oximeter, Temperature Probe, Flow Sensor,
 Ambulatory Blood pressure Monitor,
 Defibrillator/Monitor and Accessories, Electrocardiograph,
 Anesthesia Machine and accessories, Ventilator,
 Air compressor, Endoscope Camera System,
 Ultrasonic Diagnostic Equipment and Accessories,
 Digital Radiography System, Radiography System,
 Hematology Analyzer, Clinical Chemistry Analyzer,
 Urine Analyzer, Microplate Reader,
 Microplate Washer for invitro diagnostic use,
 Chemiluminescence Immunoassay Analyzer,
 Flow Cytometer, (Auto) Sample Processing System,
 Auto Slide Maker&Stainer, Glycohemoglobin Analyzer,
 Specific Protein Analyzer, Reagents for Hematology Analyzer,
 Reagents for Clinical Chemistry Analyzer,
 Chemiluminescence Immunoassay Reagents,
 Chemiluminescence Immunoassay Calibrators and Controls,
 Reagents for Flow Cytometer,
 Reagents for Glycohemoglobin Analyzer,
 Calibrators and Controls for Glycohemoglobin Analyzer,
 Disposable Anesthesia Mask, Reusable Anesthesia Mask,
 Respiratory Mask, Disposable Breathing Circuit,
 Reusable Breathing Circuit, Heat and Moisture Exchanger,
 Filter, Breathing Bag.

December 29th, 2020

LETTER OF DECLARATION

To whom it may concern,

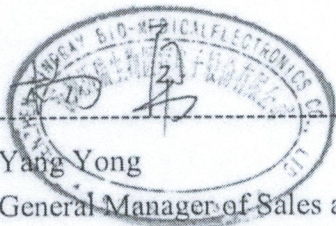
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("Mindray")
manufacturer of Hematology analyzer **BC-30s**, do hereby declare that:

The following reagents:

- A12-000047 M-30D DILUENT
- A12-000084 M-30CFL LYSE
- 105-000405-00 Probe Cleanser
- 105-003223-00 SC-CAL PLUS Calibrator 2×3.0ml
- 105-003227-00 BC-3D Control 3 x 3.0ml Tri-pack(1L, 1N, 1H)

Are manufactured by our company exclusively for the use with the closed-system BC-30s
Hematology Analyzers.

Sincerely yours,



Yang Yong

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

Сертификат

Poiata Vitalie

компания: SRL Biosistem MLD

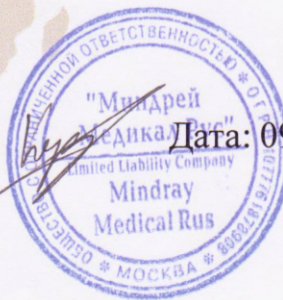
Пройден технический тренинг по курсу:

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

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Центр поддержки клиентов Mindray Medical Russia Ltd.



Дата: 09 октября 2015 года

Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

Пройден технический тренинг по курсу:

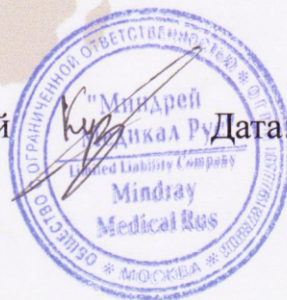
- Автоматический гематологический анализатор BC-5150
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.



EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: Fecal Occult Blood (FOB) Test
Brand: Rapidan® Tester, Toyo®, Info®, Labmen®
Classification: Professional Use IVD, 98/79/EC
Conformity Assessment Route: Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Revision No: 5

Place, Date of Issue: İzmir, 08.03.2019

Signature Dr. Şahin Yağlıdere, Md
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 FAX: 0 232 376 80 40
MENDERES V.D/ 079 009 6209





CERTIFICATE

No J - 2670/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of 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 **22.12.2020 to 21.12.2023**

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No J - 2670/4/2020

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020

Date of certification decision: 14.10.2020

Certificate bears a qualified signature.

Warsaw, 15.10.2020

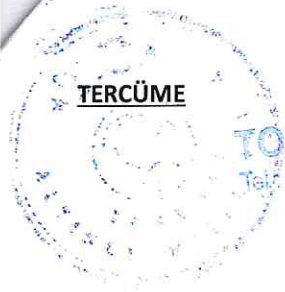


AC 019
QMS



Member of the Board

SOĞUK DAMGA VARDIR



T.C.
TORBALI 6. NOTERLİĞİ
Telf: 0232 664 70 07 Fax: 0232 664 70 17



№ 09971

SERTİFİKA

No. M – 56/4/2020

İşbu sertifika ile;

TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No:2, Tekeli-Menderes
İzmir, Türkiye

ve sertifika ekinde listelenmiş

Lokasyon

Aşağıdaki faaliyetler kapsamında

EN ISO 13485:2016

ile uyumludur:

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kendi kendine test ve profesyonel kullanım için tasarlanmış hızlı testler, kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri) ve EKG elektrotları

Polonya Test ve Sertifikasyon Merkezi tarafından yürütülen denetim, yukarıdaki kanıtları sağlamıştır. Bu Sertifika, Kuruluş tarafından yukarıdaki standarda uyulması kaydıyla geçerliliğini koruyacaktır.

Bu sertifikanın geçerlilik tarihi: 22.12.2020'den 21.12.2023'e kadar

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020

Sertifika kararının tarihi: 14.10.2020

Sertifika, yetkili imzayı taşımaktadır.

Varşova, 15.10.2020

Anna <<Elektronik İmza>>
Malgorzata
Wyroba
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

10 3 Aralık 2020





CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of 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 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

Anna
Małgorzata
Wyroba
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:00:16 +02'00'

PARTNER OF
IONet



AC 019
QMS





№ 09971

SERTİFİKA EKİ**SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR**
No. M – 56/4/2020

İşbu sertifika, aşağıda yer alan faaliyetler kapsamında Lokasyonun tasdiki için hazırlanmıştır:

Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-Menderesizmir, Türkiye**invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri), profesyonel kullanım IVD testleri ve EKG elektrotları****Sertifikada listelenen standardın gereksinimlerini karşılar.**Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020
Sertifika kararının tarihi: 14.10.2020
Sertifika, yetkili imzayı taşımaktadır.
Varşova, 15.10.2020Anna <<Elektronik İmza>>
Malgorzata
Wyroba
Yönetim Kurulu ÜyesiPOLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
Sema ZİYREK



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

№ 09971

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



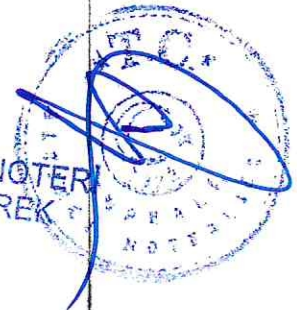
AC 019
QMS



Anna
Małgorzata
Wyroba
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:02:27 +02'00'

T.C.
TORBALI 6. NOTER
Seim ZIYREK





CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
rapid tests intended for self-testing and for professional use,
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of 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 **22.12.2020** to **21.12.2023**

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020



AC 019
QMS



Member of the Board



ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control
and distribution of in vitro medical devices:
reagents and reagent products for blood grouping
(gel cards and red blood cells reagents),
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020

Date of certification decision: 14.10.2020

Certificate bears a qualified signature.

Warsaw, 15.10.2020



AC 019
QMS



Member of the Board