ORDIN DE PLATA NR.: 912 TIP.DOC. 1

DATA EMITERII:20 septembrie 2021

PLATITI: 10500-00 LEI: Zece Mii Cinci Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329

BENEFICIAR (R) Centrul pentru achizitii publice centralizate in sanatate
CONTUL DE PLATI/CODUL IBAN MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR
Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII: :TREZMD2X

DESTINATIA PLATII:/P102/10500,00 Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1629: 120138856 din 21.09.2021

TIPUL TRANSFERULUI: NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:20/09/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.09.20 16:53:40 EEST
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2115192 **din** / от 08.09.2021

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil pînă la / Действителен до 23.09.2021

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

Șef DDF Rîșcani
a DGAF mun.Chișinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUȘ
Numele și prenumele/Фамилия и имя

L.Ș/ M.П.

Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 08.09.2021 ora 14:25:51
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: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 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 MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

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 şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

Дата предоставления 11.05.2021 10:00:47

Anexe 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 CUIÎO: 40717392
Cod IDNO: 1010600028048

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

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele și coordonatele al contabilului-șef: Dl (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

la

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul 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. concesiuni, 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. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2204135	2791637
	3.4. mijloace de transport	084		
	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	4458	2000
A.	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 neafiliate	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 participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe 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. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4337729	3912218
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	166486	74631
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350	4	2
B.	7. Alte active circulante	360	1647908	5756117
	Total creanțe 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 neafiliate	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 participare	393		
	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 nelnregistrat	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	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
C.	**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	600		
	VI. Alte elemente de capital propriu	610		
	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		
D.	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	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		
	din care: 2.1. Împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: Împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	1331928	3252667
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	159545	188105
	6. Datorii față de personal	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/clienților	840		
F.	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 pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	27319617	25963175
din care: venituri din vînzarea 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 vînzări	016		
Costul vînzărilor, total	020	15672962	15186814
din care: valoarea contabilă a produselor și mărfurilor vîndute	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 vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuire	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 dobînzi	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 dobînzile	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) pînă 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 pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010				
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	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				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	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 pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi 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 vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi 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 nerezidenților	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 sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчёта 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.

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 11.05.2021 10:00:47

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

Către Grupul de lucru pentru evaluarea
Procedurii de achiziție nr. ocds-b3wdp1-MD-1629120138856
Din 26 aug 2021, 13:00 - 21 sept 2021, 13:00
din cadrul CAPCS

Declarație

Prin prezenta, SRL „Biosistem-mld", declara ca :

- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora.
- Termenul de valabilitate restant (la momentul livrării) va constitui minim 80% din termenul total al produsului, dar nu mai mic de 12 luni
- Va prezenta monstre, în termen de 5 zile de la solicitarea autorității contractante

_____Vitalie Poiata

L.Ș.

Rapidan® Tester

INSTRUCTION FOR USE
HBsAg Test, WB/S/P
HBsAg Detection in
Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTHB04

Hepatitis B Virus Surface Antigen Cassette Test

BACKGROUND INFORMATION
Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E. Of the many viral causes of human hepatitis few are of greater global importance than hepatitis B virus (HBV). Hepatitis B is a serious and common infectious disease of the liver, affecting millions of people throughout the world.
The severe pathological consequences of persistent HBV infections include the development of chronic hepatic insufficiency, cirrhosis, and hepatocellular carcinoma (HCC). In addition, HBV carriers can transmit the disease for many years. Infection occurs very often in early childhood when it is asymptomatic and often leads to the chronic carrier state. Detection of hepatitis B surface antigen (HBsAg) identifies individuals infected with the hepatitis B virus. Serum HBV DNA concentrations quantified by real-time polymerase chain reaction (PCR) correlate with disease progression and for decisions to treat and subsequent monitoring. HBsAg is typically detected by sensitive immunoassays that uses antibody to hepatitis B surface. Point-of-care testing offers significant advantages which include reduction of facility costs, rapid delivery of results, early diagnosis, nurses or technicians with a minimum of training, peripheral health care level and rapid initiation of treatment.

Interpretation of the Hepatitis B Panel		
Tests	Results	Interpretation
HBsAg, anti-HBc, anti-HBs	Negative, negative, negative	Susceptible
HBsAg, anti-HBc, anti-HBs	Negative, positive, positive	Immune due to natural infection
HBsAg, anti-HBc, anti-HBs	Negative, negative, positive	Immune due to hepatitis B vaccination **
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, positive, negative	Acutely infected
HBsAg, anti-HBc, IgM anti-HBc, anti-HBs	Positive, positive, negative, negative	Chronically infected
HBsAg, anti-HBc, anti-HBs	Negative, positive, negative	Four interpretations possible *

* Four Interpretations: 1. Might be recovering from acute HBV infection. 2. Might be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum. 3. Might be susceptible with a false positive anti-HBc. 4. Might be undetectable level of HBsAg present in the serum and the person is actually chronically infected.
** Antibody response (anti-HBs) can be measured quantitatively or qualitatively. A protective antibody response is reported quantitatively as 10 or more milliinternational units (≥10mIU/mL) or qualitatively as positive. Post-vaccination testing should be completed 1-2 months after the third vaccine dose for results to be meaningful.

DEFINITIONS
* Hepatitis B Surface Antigen (HBsAg): A serologic marker on the surface of HBV. It can be detected in high levels in serum during acute or chronic hepatitis. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection.
* Hepatitis B Surface Antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
* Total Hepatitis B Core Antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.
* IgM Antibody to Hepatits B Core Antigen (IgM anti-HBc): This antibody appears during acute or recent HBV infection and is present for about 6 months.

INTENDED USE
HBsAg Test is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human whole blood / serum / plasma.

REAGENTS
Anti-HBs monoclonal antibody, goat anti-mouse IgG polyclonal antibody and anti-HBs monoclonal antibody conjugated with colored particles.

METHOD
HBsAg Test uses immunochromatographic technology for the qualitative detection of HBsAg in human whole blood / serum / plasma. Sample is introduced from sampling pad. If there is HBsAg in the sample at detectable level, HBsAg binds to the mobile anti-HBs monoclonal antibodies conjugated with colored particles. Together they move to the test area "T". A visible colored signal due to the accumulation of colored particles in the test area "T" (a colored test line) indicates positive test result. If there is no HBsAg in the sample at detectable level then sample moves to the test area "T" together with unbound anti-HBs monoclonal antibodies conjugated with colored particles. Therefore, there is no visible colored signal in the test area "T" (no colored test line) be obtained, indicating negative test result. Regardless of HBsAg content of the liquid sample, accumulation of colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line always appears in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS
1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. The test is designed for whole blood / serum / plasma samples. Using other types of samples may cause invalid or false results.
4. Do not use test kit beyond the indicated expiry date. The test device is single use. Do not reuse.
5. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
6. Use a new pipette for each sample. Close the buffer bottle cap after using. Buffer is stable until expiry date after the first use in routine.
7. Adequate lighting is required to read the test results.
8. The test device should be discarded in a proper biohazard container after testing.
9. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. Do not freeze and thaw the serum, plasma samples repeatedly. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
12. Do not use turbid, hemolyzed samples. Turbid test samples should be centrifuged.
13. Hemolytic samples should not be used since they can lead to invalid or false results.
14. A negative result does not exclude the possibility of HBV infection. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is required.
15. A false negative result can occur in the following a recent exposure to HBV; the recent exposure may take several months to reach detectable levels due to recent infection. In exceptional cases; presence of mutant virus and infection with a variant of the virus may lead to observation of false negative results.
16. Positive samples should be retested using another method and the results should not be used as the only basis for the diagnosis of hepatitis viral infection.
17. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE
Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze. The test in the original packaging retains stable until expiry date at storage conditions.
The test device should be used in maximum one hour after the foil is opened.
Kit components : Test cassettes, pipettes, diluents (for whole blood samples only) and instructions for use.
Additional materials required but not provided : Sample collection tube, centrifuge, timer, for fingerstick whole blood: sterile lancet and capillary tubes.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION
The test can be performed using whole blood (venous blood and capillary blood), serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible and tested immediately after collection. If the sample cannot be tested on the day of collection, serum or plasma samples should be refrigerated at 2 to 8°C for up to 3 days prior to testing. If testing within 3 days is not possible, serum or plasma samples should be frozen at -20°C or colder. Frozen serum, plasma samples must be completely thawed and mixed well prior to testing. Bring the samples to room temperature before testing.
Plasma and venous blood can be collected with the following anticoagulants: K3EDTA, K2EDTA, sodium citrate (3,2%), sodium citrate (3,8%), lithium heparin, sodium heparin.
Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Plasma Samples: Collect blood into a collection tube with anticoagulants to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma (Centrifugation time & speed: 2300-2880 x g for ~ 10 min).
Whole Blood Samples: Collect venous blood into a collection tube with anticoagulants to avoid coagulation, test should preferably be performed immediately. Otherwise, whole blood samples should be stored at 2 - 8 °C until they are being tested in a period of 2 days after collection. Do not freeze whole blood sample.
For Capillary Blood; according to the laboratory practice, use a sterile lancet and an appropriate capillary tube to collect blood by capillary action. Test should be performed immediately.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. **For Serum / Plasma Samples:** Draw serum / plasma into pipette and put 3 drops (75 µl) into the sample well of the cassette. Do not use diluent for serum / plasma samples.

For Whole Blood Samples: Draw whole blood into pipette and put 2 drops (50 µl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

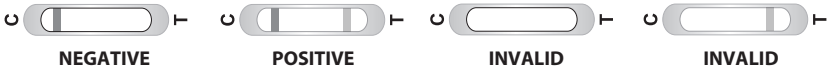
When using Capillary Blood Samples: Collect 50 µl of fingerstick whole blood using the capillary tube (not provided) and transfer it into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

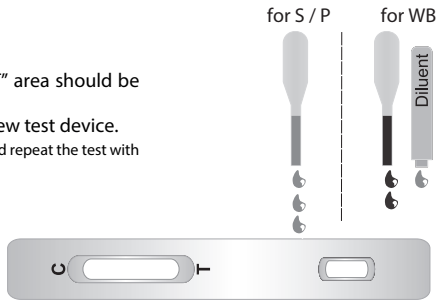
Avoid the formation of any air bubbles.

3. Results should be read at 15 minutes as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area.
Positive: Two colored lines are visible in "C" and "T" areas.
Low concentration of hepatitis B surface antigen may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid: No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.





QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

HBsAg Test can detect all subtypes of hepatitis B virus surface antigens.

Sample Status	Sample HBsAg Status	S / P Sample Type			WB Sample Type		
		Study Number	Com. Assay	Result	Study Number	Com. Assay	Result
Naturally acute or chronic infected	Positive	536	EIA	100 %	411	EIA	100 %
Blood donors	Negative	1041	EIA	99,8 %	-	-	-
Clinical samples	Negative	225	EIA	100 %	225	EIA	100 %
Pregnant women	Negative	280	EIA	100 %	30	EIA	100 %

Sensitivity and Specificity

Using results of positive samples (947/947) and negative samples (1799/1801); sensitivity, specificity with the 95% confidence interval values are calculated as;

Sensitivity : 100 % [95% CI = 99,61% - 100%] Specificity : 99,89 % [95% CI = 99,60% - 99,99%]

Analytical Sensitivity Cut-off: 0,26 IU/mL

Seroconversion panels: 30 seroconversion panels were studied with Türklab HBsAg Test and compared to results from CE Marked EIAs as reference assays. Türklab HBsAg Test was capable of detecting antigens of HBsAg in a similar manner of the CE Marked EIA tests.

Interferences: Following potentially interfering substances were tested with HBsAg Test: Hemoglobin, Bilirubin, Triglycerides, Rheumatoid Factor (RF). No interference was observed.

Hemolytic samples should not be used since they can lead to invalid or false results.

Cross Reactivity: Cross reactivity has been tested with below samples, no cross reactivity was found with the HBsAg Test.
- Anti-HCV serum / plasma samples,
- Anti-HBs serum / plasma samples,
- Whole blood / serum / plasma samples from pregnant women.

Capillary Blood: Positive and negative capillary whole blood specimens collected by fingerstick were performed with HBsAg Test. The results showed that there was a good correlation of testing results between venous whole blood and capillary blood.

REFERENCES

1. "Hepatitis B", *World Health Organization Department of Communicable Diseases Surveillance and Response*, WHO/CDS/CSR/LYO/2002.2:Hepatitis B.
2. "Hepatitis B", *WHO, Media Centre*.
3. "Facts and Figures", *The Hepatitis B Foundation*.
4. Interpretation of Hepatitis B Serologic Test Results, *Centers for Disease Control and Prevention (CDC)*.
5. Guidelines fort he prevention, care and treatment of persons with chronic hepatitis infection, *World Health Organization*, 2015.
6. Khuroo MS, Khuroo NS, Khuroo MS. (2014). "Accuracy of Rapid Point-of-Care Diagnostic Tests for Hepatitis B Surface Antigen—A Systematic Review and Meta-analysis". *Journal of Clinical and Experimental Hepatology*. doi:10.1016/j.jceh.2014.07.008.
7. WHO Guidelines on Hepatitis B and C Testing. Geneva: World Health Organization; 2017 Feb. ANNEX 4, *PICO Questions and Decision-Making Tables.*

TÜRKLAB let us diagnose

TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.
ITOB 10017 Sokak No: 2 Tekeli Menderes / Izmir / TURKEY
T: +90 232 376 80 81 • F: +90 232 376 80 40 • www.turklab.com.tr • info@turklab.com.tr

CE 1434

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date

CERTIFICATE

EC No 1434-IVDD-434/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 56/2019
Module: H6

Certificate No **1434-IVDD-434/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

CERTIFICATE

EC No 1434-IVDD-435/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, 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 requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

The date of the first issue of the Certificate: 29.08.2008

CE 1434

Michał Pachowski, PhD
President

Application No: 56/2019
Module: H7

Certificate No **1434-IVDD-435/2019**
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

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 affored 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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Małgorzata Wyroba
Member of the Board

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:47:33 +02'00'

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

Member of Multilateral Recognition Arrangement IAF

Anna Małgorzata Wyroba
Member of the Board

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:48:40 +02'00'

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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 cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored 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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Małgorzata Wyroba
Member of the Board

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

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

SOĞUK DAMGA VARDIR

TERCÜME

T.C.
TORBALI 6. NOTERLİĞİ
Tel: 0232 854 70 07 Fax: 0232 854 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 herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

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

№09971

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 cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored 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

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

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

Anna Małgorzata Wyroba
Member of the Board

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

TERCÜME

№09971

SERTİFİKA EKİ

SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR

No. M – 56/4/2020

İşbu sertifika, aşağıda yer alan faaliyetler kapsamındaLokasyonun tasdiki için hazırlanmıştır:

Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-Menderesİzmir, 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, 15.10.2020

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

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İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
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:

№0971

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

T.C.
TORBALI 6. NOTER
Selma ZİYREK

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

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019
QMS

IAF

Anna Małgorzata Wyroba

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

Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl