ORDIN DE PLATA NR.: 2663 TIP.DOC. 1

DATA EMITERII:mar?i, 27 februari

PLATITI: 9800-00 LEI: Noua Mii Opt Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL
CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

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

BENEFICIAR (R) IMSP CS Bri ceni
CONTUL DE PLATI/CODUL IBAN
MD92AG0000000225126229 05
CODUL FISCAL :1007604006440 /

PRESTATORUL BENEFICIAR
BC"MOLDOVA-AGROINDBANK"S.A.
CODUL BANCII:
:AGRNMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1707925886931 din 29.02.2024

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:27/02/2024
DATA EXECUTARII:
SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAAEDi65avx+fXSldAAAAAQOLMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTI0MDEyNTExMzM1NloXDTI3MDEyNTExNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAAEDijjVd7aJ5r0rAAAAAQOKMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTI0MDEyNTExMzMzNVoXDTI3MDEyNTExNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

L.S. (semnatura electronica)

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2024.02.28 17:08:06 EET
Reason: MoldSign Signature
Location: Moldova

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1221048**

Din От **23.02.2024 12:21**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **09.03.2024 12:21**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **23.02.2024 12:21**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

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

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

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 (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
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, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

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: **15.09.2023**.

Registrator în domeniul înregistrării de stat

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova

Rusu Diana

EB 0461494

Date cu caracter personal

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

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, 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 activităţii de întreprinzător***", cu modificarile ulterior adoptate de parlamentul RM, ***Importul, comercializarea, asistenţa tehnică si reparaţia 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.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA

_____Vitalie Poiata

L.Ş.

adresa: str. Albișoara 16/1 of.7, MD-2001 Chișinău, Republica Moldova
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Дата предоставления 28.03.2023 14:26:11

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

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: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la

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		
	din care: 2.1. concesiuni, licențe și mărci	021		
	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		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	3559998	3384131
	din care: 3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	3533108	3363063
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085	26890	21068
	3.6. alte mijloace fixe	086		
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120	1162136	5250844
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	4722134	8634975
	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	4722134	8634975
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	5346	13899
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	9147976	11123640
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	9153322	11137539
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2182471	4552459
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	208171	27696
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	1608597	2268111
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	3999239	6848266
	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	9861933	10281443
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	23014494	28267248
	TOTAL ACTIVE (rd.230 + rd.420)	430	27736628	36902223
	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	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
C.	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	26634334	22485398
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	13391573
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	26634334	35876971
	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	26639734	35882371
	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		

E.	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	343711	5266
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	355528	143160
	6. Datorii față de personal	760	350	866
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	150263	831429
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	247042	39131
	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	1096894	1019852
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	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	27736628	36902223

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2022 pînă la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	38680547	40621876
din care: venituri din vînzarea produselor și mărfurilor	011	37724557	39203671
venituri din prestarea serviciilor și executarea lucrărilor	012	951393	1390733
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vînzări	016	4597	27472
Costul vînzărilor, total	020	24434231	22086174
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	24433364	21991682
costul serviciilor prestate și lucrărilor executate terților	022		92356
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026	867	2136
Profit brut (pierdere brută) (rd.010 - rd.020)	030	14246316	18535702
Alte venituri din activitatea operațională	040	5189	128694
Cheltuieli de distribuire	050	6076	15271
Cheltuieli administrative	060	1788732	3076978
Alte cheltuieli din activitatea operațională	070	1870642	1325483
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10586055	14246664

Venituri financiare, total	090	1517765	1530710
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093	30619	250190
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	1487146	1280520
Cheltuieli financiare, total	100	249562	512939
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	249562	512939
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1268203	1017771
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	1268203	1017771
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	11854258	15264435
Cheltuieli privind impozitul pe venit	170	1450263	1872862
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	10403995	13391573

SITUAŢIA 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				
	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				

SITUAŢIA 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)

Версия для печати
Сохранить

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2022
Дата предоставления: 28.03.2023
Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 28.03.2023 14:26:11

Версия для печати
Сохранить

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2022
Дата предоставления: 28.03.2023
Временная метка отчёта зарегистрированного в Информационной Системе НБС : 28.03.2023 14:55:24

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

BioSystems
REAGENTS & INSTRUMENTS

CERTIFICAT DE AUTORIZARE

Prin prezentul este autorizata

SRL Biosistem-MLD
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica Moldova produsele

BIOSYSTEMS SA
cu sediul C/Costa Brava 30
08030 Barcelona (Spain)

Xavier Palomar
Area Manager
27-April-2013

BioSystems
Costa Brava, 30
08030 BCN

Inscrita R.M. Barcelona, tomo 4.538, folio 127, hoja 48.411, libro 3.864, Sección 2ª N.I.F. A08678823

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com

BioSystems
REAGENTS & INSTRUMENTS

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

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

Inscrita R.M. Barcelona, tomo 4.538, folio 127, hoja 48.411, libro 3.864, Sección 2ª N.I.F. A08678823

CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

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
REAGENTS & INSTRUMENTS

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

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

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

BioSystems
Costa Brava, 30
08030 BCN

Xavier Palomar
Area Manager
27-April-2011

Inscrita R.M. Barcelona, tomo 4.538, folio 127, hoja 48.411, libro 3.864, Sección 2ª N.I.F. A08678823

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:
We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

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

Product Category(ies): Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer,Urinalysis reagent strips.

Products: Attachment I

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

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, **2016-09-01**

Chuanbin Tan

Signatory name: Chuanbin Tan
signatory title: Technical Regulation Manager
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MD IDNO 1010600028048 REPUBLICA MOLDOVA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

ATTACHMENT I

Product Name	Product Model	Accessories
Hematology Analyzer	BC-2300、 BC-2100	M-23CFL LYSE M-23D DILUENT M-23E E-Z CLEANSER M-23P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-1800、 BC-1900、 BC-2900	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator BC-3D Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-3000 Plus	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3200、 BC-3200CT	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500、	M-50D DILUENT

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

	BC-5200	M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300、BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5380、BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800、BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MOLD IDNO 1006600028048 REPUBLICA MOLDOVA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hemalology Control
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. BioSistem MLD IDNO 1010600028 REPUBLICA MOLDOVA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150、BC-5000、HM-500X	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator
Urine Analyzer	UA-66、UA-600、UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、BC-21s、BC-30s、BC-31s、HM-200X	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

		Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent	/	/
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen 518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel：+86 755 26582888
Fax: +86 755 26582500

		Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、BS-180	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem ML IDNO 1010600078048 REPUBLICA MOLDOVA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel：+86 755 26582888
Fax: +86 755 26582500

		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、BS-800M、BS-820M、BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System（RMS）
Chemistry Analyzer	BS-2000、BS-2000M、BS-2200、BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System（RMS）

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen 518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemistry Analyzer	BS-480、BS-490	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Built-in sample/reagent bar code reader Remote management system (RMS) Water supply module External air pump
Chemistry Analyzer	BS-430、BS-450、BS-460	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
α-Amylase（α-AMY）Kit（IFCC Method）	/	/

SOCIETATEA CU RASPUNDERE LIMITATA
BIOSYSTEM MLD S.R.L.
IDNO 1010800028048
REPUBLICA MOLDOVA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Aspartate Aminotransferase（AST）Kit（IFCC Method）	/	/
Gamma-Glutamyltransferase（GGT）Kit（Szasz Method /IFCC stand.）	/	/
Lactate Dehydrogenase（LDH）Kit（IFCC Method）	/	/
Alanine Aminotransferase（ALT）Kit（IFCC Method）	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromcresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
α-Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turibidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N Multi Control Sera P	/	/
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N Lipids Control P	/	/
CK-MB Control N CK-MB Control p	/	/
Specific Proteins Control N Specific Proteins Control P	/	/
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/
Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbuimn (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimmun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α-L-Fucosidase Kit (CNPF method)	/	/
5′-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β2-MG Calibrator	/	/
β2-MG Control	/	/
Free Triiodothyronine（CLIA）	/	/
Free Thyroxine（CLIA）	/	/
Total Triiodothyronine（CLIA）	/	/
Total Thyroxine（CLIA）	/	/
Thyroid-stimulating Hormone（CLIA）	/	/
Follicle Stimulating Hormone（CLIA）	/	/
Luteinizing Hormone（CLIA）	/	/
Prolactin（CLIA）	/	/
Estradiol（CLIA）	/	/
Estriol（CLIA）	/	/
Testosterone（CLIA）	/	/
Progesterone（CLIA）	/	/
Total β Human Chorionic Gonadotropin（CLIA）	/	/
Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total β HCG Calibrators	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen（CLIA）	/	/
Alpha-fetoprotein（CLIA）	/	/
Cancer Antigen 125（CLIA）	/	/
Cancer Antigen 15-3（CLIA）	/	/
Carbohydrate Antigen 19-9（CLIA）	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin（CLIA）	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" （ASO）Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C（CysC)Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein（FR-CRP）Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor（RF）Kit(Immunoturbidimetric Method）	/	/
Rheumatoid Factor Calibrator	/	/
β2-Microglobulin（β2-MG） Kit (Latex Immunoturbidimetric Method)	/	/
β2-Microglobulin Control	/	/
β2-Microglobulin Calibrator (for Serum)	/	/
β2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobubin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β-Hydroxybutyrate (β-HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit （Particle-enhanced Immunoturbidimetric Assay Method）	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
β-HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β-HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I(CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide(CLIA)	/	/
BNP Calibrators	/	/
Myoglobin(CLIA)	/	/
MYO Calibrators	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotropic hormone(CLIA)	/	/
ACTH Calibrators	/	/
Cardiac Marker Multi Control	/	/
Thyroid Function Multi Control	/	/
Immunoassay Multi Control	/	/
ACTH Control	/	/
Anti-thyroid Antibodies Control	/	/
System Detection Solution	/	/
System Wash Solution	/	/
ClinChem Multi Control (level 1)	/	/
ClinChem Multi Control (level 2)		
Sample Diluent	/	/
HCY Control	/	/
Homocysteine (HCY) Kit (Enzymatic Cycling Method)	/	/
Total Protein in Urine/CSF(TPUC) Kit (Pyrogallol Red-Molybdate Method)	/	/
TPUC Control	/	/
25-OH-Vitamin D Total (CLIA)	/	/

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

25-OH-Vitamin D Total Calibrators	/	/
Parathyroid hormone (CLIA)	/	/
PTH Calibrators	/	/
Calcitonin (CLIA)	/	/
Calcitonin Calibrators	/	/
Folate(CLIA)	/	/
Folate Calibrators	/	/
Vitamin B12(CLIA)	/	/
Vitamin B12 Calibrators	/	/
Metabolic Multi Control	/	/
Red Blood Cell Folate Releasing Reagent	/	/
Cancer Antigen 72-4 (CLIA)	/	/
Neuron-specific enolase (CLIA)	/	/
CYFRA 21-1 (CLIA)	/	/
Antibody to Treponema pallidum (CLIA)	/	/
CA72-4 Calibrators	/	/
Cyfra21-1 Calibrators	/	/
Anti-TP Calibrators	/	/
NSE Calibrators	/	/
Tumor Marker Multi Control	/	/
NSE Control	/	/
Anti-TP Control	/	/

Declaration of Conformity V 1.0

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-5000**
Including reagents as following:
M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26
Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

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-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26

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

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

CIS-DL-LI373-66601931

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-5150,** do hereby declare that:

The following reagents:

- 105-004045-00 M-52D Diluent
- 105-003724-00 M-52DIFF Lyse
- 105-004307-00 M-52LH Lyse
- 105-002225-00 M-68 Probe Cleanser
- 105-003233-00 BC-5D High/Normal/Low/EN3ml*3

Are manufactured by our company exclusively for the use with the closed-system BC-5150 Hematology Analyzers. The usage of reagents is also described in the user manual of the analyzer at the point: "*2.7. Reagents, Controls and Calibrators*", *page 2-12.*

Sincerely yours,

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

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 002596 0002 Rev. 01

Holder of Certificate: **Lansion Biotechnology Co., Ltd.**
No.2 Qiande Road, Science Park, Jiangning District
210000 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Lansion Biotechnology Co., Ltd.
No.2 Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate.

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Dry Fluorescence Immunoassay Analyzer, Dry Fluorescence Immunoassay test kit, Coagulation Test Kit(Electrochemistry), Handheld coagulation Analyzer**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 002596 0002 Rev. 01

Report No.: SH20126602
Valid from: 2021-04-12
Valid until: 2024-04-02

Date, 2021-04-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
Loc. Campiano, 9/B – 47867 Talamello (RN)
e.mail: info@biogroupmedicalsystem.com
Tel. +39 0541 920686
Fax +39 0541 922130

To: Whoever it may concern

Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

04.12.2019

LETTER OF AUTHORIZATION

We, **BIO GROUP MEDICAL SYSTEM** Srl located in Loc. Campiano 9B Talamello (RN) Italy VAT IT00964170419, do hereby authorize:

Biosistem-mld SRL with business office at Albisoara 16/1 ap.7 , Chisinau, Republic of Moldova

to be our official representative to submit bids, and subsequently negotiate and sign contracts for procurement of External quality controls for hematology in Republic of Moldova.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

The Executive Manager
Adelmo Ciccioni

BIO GR
MEDICAL SYSTEM SRL
Loc. Campiano 9/B - 47867 Talamello (RN)
P.iva / C.Fisc.: 00964170419

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO DI ACCREDITAMENTO
Accreditation Certificate

ACCREDITAMENTO N. / *ACCREDITATION N.* **0017P** REV. **00**

EMESSO DA / *ISSUED BY* **DIPARTIMENTO LABORATORI DI PROVA**

SI DICHIARA CHE / *WE DECLARE THAT* **BIO-GROUP MEDICAL SYSTEM S.r.l.**
Sede/Headquarters:
- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI DELLA NORMA: UNI CEI EN ISO/IEC 17043:2010

MEETS THE REQUIREMENTS OF THE STANDARD: *ISO/IEC 17043:2010*

QUALE / *AS*: **Organizzatori di prove valutative interlaboratorio** / ***Proficiency Testing Provider***

MD-CA-01 rev. 03

Data di 1ª emissione *1st issue date* **14-11-2018**	Data di modifica *Modification date* **14-11-2018**	Data di scadenza *Expiring date* **13-11-2022**
Dott.ssa Silvia Tramontin Il Direttore di Dipartimento *The Department Director*	Dott. Filippo Trifiletti Il Direttore Generale *The General Director*	Ing. Giuseppe Rossi Il Presidente *The President*

L'accreditamento attesta la competenza tecnica dell'Organizzazione relativamente al campo di accreditamento riportato nell'Elenco Schemi allegato al presente certificato di accreditamento.
Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi, che possono variare nel tempo.
La vigenza dell'accreditamento può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure.
The present certificate is valid only if associated to the annexed schedule, that may vary in the time.
Confirmation of the validity of accreditation can be verified on website www.accredia.it or by contacting the relevant Department.

ACCREDIA

Sede operativa e legale: Via Guglielmo Saliceto, 7/9 | 00161 Roma - Italy | Tel. +39 06 8440991 | Fax +39 06 8841199
info@accredia.it | www.accredia.it | Partita IVA - Codice Fiscale 10566361001

BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
Loc. Campiano, 9/B – 47867 Talamello (RN)
e.mail: info@biogroupmedicalsystem.com
Tel. +39 0541 920686
Fax +39 0541 922130

Declaration of conformity certificate
We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47867 Italy
Ensure and declare with sole responsibility that the products:

Internal code: MSEQUALITYCH-MSEQSCH12-MSEQSCH4 EDMA Code: 38220000	Commercial name: QS Clinical Chemistry First lot introduced in market: 112-NB
Internal code: MSEQUALITYPS EDMA Code: 38220000	Commercial name: QS Specific Protein First lot introduced in market: 220-NB
Internal code: MSEQUALITYEF EDMA Code: 38220000	Commercial name: QS Electrophoresis First lot introduced in market: 220-NB
Internal code: MSEQUALITYE8-MSEQSE12 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC-MSEQSC12-MSEQSC4 EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI-MSEQSI12-MSEQSI4 EDMA Code: 38220000	Commercial name: QS Immunology First lot introduced in market: 360
Internal code: MSEQUALITYB EDMA Code: 38220000	Commercial name: QS Bacteriology First lot introduced in market: 326
Internal code: MSEQUALITYS EDMA Code: 38220000	Commercial name: QS Serology First lot introduced in market: 1020-SI
Internal code: MSEQUALITYU EDMA Code: 38220000	Commercial name: QS Urine First lot introduced in market: 002-U
Internal Code: MSEQUALITYH-MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBA1C First lot introduced in market: 001-H
Internal Code: MSEQUALITYD EDMA Code: 38220000	Commercial name: QS Drug of Abuse First lot introduced in market: 330-D
Internal Code: MSEQUALITYSO EDMA Code: 38220000	Commercial name: QS FOB First lot introduced in market: 110-F
Internal Code: MSEQUALITYESR EDMA Code: 30021095	Commercial name: QS ESR First lot introduced in market: 001-V
Internal Code: MSEQUALITYCM EDMA Code: 38220000	Commercial Name: QS Cardiac Marker First lot introduced in market: 201-C

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.
To this purpose, we guarantee and declare, on our own responsibility, what follows:

- Subsequent lots will be consistent with technical specification of the first lot. This conformity will be attested on the quality control certificate.
- The specified item satisfy the all dispositions applicable of Directive 98/79/CE
- We undertake in storing and placing to the competent Authority disposal the technical dossier of the product, as required by Council Directive 98/79/CE, annex III, as well as the production and control registrations for a period of at least 5 years after the last production date of the last lot.
- The specified device is designed, manufactured, and commercialized with date of first release not preceding the present one.

The present conformity declaration has validity of a maximum of 5 years.
Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.

Talamello, January the 29th, 2019

BIO GROUP
MEDICAL SYSTEM SRL
The Executive Manager
Loc. Campiano 9/B - 47867 Talamello (RN)
P.IVA C.Fisc. 00504170419

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-1100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-2100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LS-4000 Dry Fluorescence Immunoassay Analyzer (Handheld)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CK-MB Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- Myo Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- NT-proBNP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- D-Dimer Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2021
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2021
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- SAA/CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TT4 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- TSH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 09.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- AMH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- HbA1c Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- β -HCG Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 07/23/2020
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- LH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 04.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

320115093554

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- FSH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 04.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

320115093554

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PRL Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: CTO
Date: 09.02.2020
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- 25-OH-VD3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- BNP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- H-FABP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- IL-6 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 25/03/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 25/03/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- hs-cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 08/05/2021

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- Ferritin Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PGI/PGII Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 08/05/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- PCT/IL-6 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: 12/08/2021
Seal/Stamp:
Lansion Biotechnology Co., Ltd.