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ORDIN DE PLATA NR.: 167                                TIP.DOC. 1 :
                                DATA EMITERII:luni, 10 martie 20:
=====:
PLATITI: 10000-00                                LEI: Zece Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) 'BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" SRL                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP CS Bri                                CONTUL DE PLATI/CODUL IBAN :
ceni                                MD92AG0000000022512622905 :
                                CODUL FISCAL :1007604006440 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"MOLDOVA-AGROINDBANK"S.A.                                :AGRNMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1740488837660 din : :
11.03.2025 : :
: :
: : L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:10/03/2025 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONducATOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAAcCBGwggRoMIIDUKADAgECAhNHAAE Di65avx+fXSldAAAAAQOLMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzZmMREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
YDVQIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
                                (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAAcCBHAWggRsMIIDVKADAgECAhNHAAE DiJjVd7aJ5r0rAAAAAQOKMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTI0MDEyNTEyMzZmMREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
gYDVQIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
L.S.                                (semnatura electronica) :
CONducATOR:                                (semnatura manuala) :
CONTABIL-SEF:                                (semnatura manuala) :
SEMnATURA PRESTATORUL                                L.S. :
-----:

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MOTIVUL REFUZULUI : L.S. :
-----:

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: 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: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 10 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

la

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	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 immobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru immobilizări necorporale	040		
Total immobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Immobilizări corporale			
1. Immobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3384131	4438372
din care:			
3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3363063	4423127
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085	21068	15245
3.6. alte mijloace fixe	086		
4. Resurse minerale	090		
5. Active biologice immobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru immobilizări corporale	120	5250844	2337159
Total immobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	8634975	6775531
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 immobilizate			
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	8634975	6775531
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	13899	24776
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11123640	11490033
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11137539	11514809
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4552459	2646694
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	27696	45618
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2268111	2251145
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6848266	4943457
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți nefiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de 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	10281443	27361722
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	28267248	43819988

	TOTAL ACTIVE (rd.230 + rd.420)	430	36902223	50595519
	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	35876971	29813141
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	18618853
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	35876971	48431994
	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	35882371	48437394
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		
	din care:			
	2.1. Împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	5266	59765
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	143160	273711
	6. Datorii față de personal	760	866	
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	831429	1766706
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	39131	57943
	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	1019852	2158125
	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
F.	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	36902223	50595519

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
------------	---------	----------------------

		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	40621876	58891757
din care:			
venituri din vânzarea produselor și mărfurilor	011	39203671	57105542
venituri din prestarea serviciilor și executarea lucrărilor	012	1390733	1771148
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	27472	15067
Costul vânzărilor, total	020	22086174	32917436
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	21991682	32793096
costul serviciilor prestate și lucrărilor executate terților	022	92356	124340
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026	2136	
Profit brut (pierdere brută) (rd.010 - rd.020)	030	18535702	25974321
Alte venituri din activitatea operațională	040	128694	829270
Cheltuieli de distribuire	050	15271	4167
Cheltuieli administrative	060	3076978	3996115
Alte cheltuieli din activitatea operațională	070	1325483	879808
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	14246664	21923501
Venituri financiare, total	090	1530710	1070406
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	250190	337916
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	1280520	732490

Cheltuieli financiare, total	100	512939	1786338
din care:	101		
cheltuieli privind dobânzile			
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	512939	1786338
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1017771	-715932
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	1017771	-715932
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	15264435	21207569
Cheltuieli privind impozitul pe venit	170	1872862	2588716
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	13391573	18618853

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
I.	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
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)					
IV.	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	(((
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	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 vânzarea 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 sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 26.03.2024 17:05:42

Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 09.04.2024 09:26:11

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs.
Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

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

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților 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 și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

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 și a întreprinzătorilor individuali și 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



BC "MOLDINDCONBANK" S.A. Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDM2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent
in moneda nationala al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu
IBAN MD95ML000000002251429243.

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

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

Scrisoare de informare

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



Vitalie Poiata

L.Ș.



Declaration of Conformity

This is to state that Technical Documentation (CL001, rev. 2.0) for product(s)

Coaguometer

(Model:CA-01, CA-02)

(IVD products other than those covered by Annex II, IVD for self-testing and devices for Performance evaluation according to manufacturer's declaration)

Manufactured by

CLINDIAG SYSTEMS CO., LTD

No.29 Zhiyuan Road, Jurong Economic Development Zone,

Zhenjiang, Jiangsu Province, China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device



For and on behalf of
CLINDIAG SYSTEMS CO.,LTD.


.....
Authorized Signature(s)

Mr. Xu Xin

General Manager



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



EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012




Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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



AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM
(b2GP1)
Anti-Cardiolipin Antibodies (ACA-
IgG/IgM)
Anti-Centromere B Antibodies (CENP-
B)
Anti-Citrullinated Protein Antibodies
(ACPA)
Anti-Deamidated Gliadin Peptides IgA
(DGP IgA)
Anti-Deamidated Gliadin Peptides IgG
(DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies
(Anti-TPO)
Anti-tTransglutaminase IgA Antibodies
(Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies
(Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:

AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

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

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

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



Xavier Palomar
Area Manager
27-April-2011



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

Declaration of Conformity



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

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

Product: Auto Hematology Analyzer

Model: BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26

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

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity



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

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

Product: Auto Hematology Analyzer

Model: BC-5150

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

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

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

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

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Start of CE-Marking: 2013-9-26

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

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

Product: Auto Hematology Analyzer

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

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

Declaration of Conformity V 1.0

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

AMZ MEDICAL

Steenberg 66
Ninove
BELGIUM

18.12.2014

To: Whom it may concern

SERVICE TRAINING CERTIFICATE

We Clindiag Susters BVBA, located Steenberg 66, Ninove 9401, who are official manufacturers of the Clindiag laboratory products, having own Clindiag group factories at several countries, do hereby authorize Mr. Alexandr Nasedchin the representative of Biosistem-mld SRL located at Albisoara Str, 16/1 Chisinau, Moldova to provide the technical support of the Clindiag laboratory analyzers as per the following list:

1. Semi auto chemistry analyzers SA-20 & SA-10.
2. Auto chemistry analyzers FA-200 & FA-300.
3. Coagulation analyzers CA-01 & CA-02.

Romain Cieters
Manager Clindiag



CLINDIAG

Clindiag Systems BVBA

Steenberg 66

9401 Ninove - BELGIUM

Tel.: 054/250.936

Fax: 054/243.058

ON: 806.140.472



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:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

320115093554

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

320115093554

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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		

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We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China





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:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:

Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2024

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2024

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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.



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.





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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China





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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 07/23/2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 04.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 04.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: CTO

Date: 09.02.2020

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China



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:

Name of authorized signatory:
Position held in the company: General Manager

Date: 28/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.



Place: Nanjing,China

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:

Name of authorized signatory:

Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China

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:

Name of authorized signatory:

Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China

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:

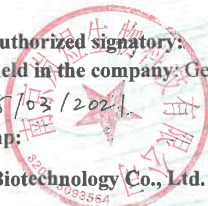
Name of authorized signatory:
Position held in the company: General Manager

Date: 25/03/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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		

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We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

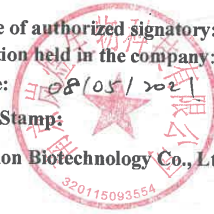
Name of authorized signatory:
Position held in the company: General Manager

Date: 08/05/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China





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:

Name of authorized signatory:
Position held in the company: General Manager

Date: 2021/05/18

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China



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:

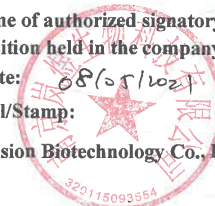
Name of authorized signatory:
Position held in the company: General Manager

Date: 2021/05/18

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China





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
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We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Name of authorized signatory:

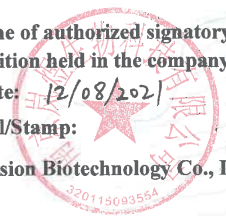
Position held in the company: General Manager

Date: 12/08/2021

Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Place: Nanjing,China





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:



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](http://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