

ORDIN DE PLATĂ

Nr.

957

DATA EMITERII

3 aprilie 2026

TIP.DOC.1

PLĂTIȚI:

12 700-00

LEI

Doisprezece mii sapte sute lei 00 bani

PLĂTITOR: (R) BIOSISTEM MLD SRL

CODUL IBAN

MD95ML00000002251429243

CODUL FISCAL

1010600028048

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP CS Briceni

CODUL IBAN

MD92AG000000022512622905

CODUL FISCAL

1007604006440

PRESTATORUL BENEFICIAR: BC'MAIB'S.A.

DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achiziție publică nr. ocds-b3wdp1-MD-1774354050805 din 06.04.2026

TIPUL TRANSFERULUI
NORMAL/URGENT/INSTANT

N

L.Ș.

CODUL TRANZACȚIEI

001

DATA PRIMIRII

DATA EXECUTĂRII

SARIVAN GABRIEL

SARIVAN GABRIEL

Document transmis prin instrument de plată electronic cu acces la
la distanță de tip internet-banking

SEMNĂTURA PRESTATORULUI

SEMNĂTURILE EMITENTULUI

L.Ș.

MOTIVUL REFUZULUI

Nota: Responsabilitatea privind veridicitatea și corectitudinea informației indicate în ordinul de plată îi revine emitentului*

*Regulamentul cu privire la transferul de credit, debitarea directă și atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





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

Data prezentării 01.04.2025 16:19:29

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2024 - 31.12.2024

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	4438372	7706354
din care:			
3.1. clădiri	081		
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	4423127	6955543
3.4. mijloace de transport	084		629606
3.5. inventar și mobilier	085	15245	9423
3.6. alte mijloace fixe	086		111782
4. Resurse minerale	090		
5. Active biologice immobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru immobilizări corporale	120	2337159	1435404
Total immobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	6775531	9141758
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	6775531	9141758
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	24776	1133
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11490033	15684462
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11514809	15685595
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2646694	4561951
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	45618	25303
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2251145	3491833
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	4943457	8079087
	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	27361722	35607750
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	43819988	59372432

	TOTAL ACTIVE (rd.230 + rd.420)	430	50595519	68514190
	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	48431994	40453271
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	25286521
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	48431994	65739792
	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	48437394	65745192
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	59765	10312
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	273711	151820
	6. Datorii față de personal	760		
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	1766706	2601490
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	57943	5376
	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	2158125	2768998
	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	50595519	68514190

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2024 până la 31.12.2024

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
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		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	58891757	72234217
din care:			
venituri din vânzarea produselor și mărfurilor	011	57105542	70297293
venituri din prestarea serviciilor și executarea lucrărilor	012	1771148	1701254
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	15067	235670
Costul vânzărilor, total	020	32917436	37551083
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	32793096	37420276
costul serviciilor prestate și lucrărilor executate terților	022	124340	130807
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	25974321	34683134
Alte venituri din activitatea operațională	040	829270	1999137
Cheltuieli de distribuire	050	4167	
Cheltuieli administrative	060	3996115	6021871
Alte cheltuieli din activitatea operațională	070	879808	692169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	21923501	29968231
Venituri financiare, total	090	1070406	970167
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	337916	255488
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	732490	714679

Cheltuieli financiare, total	100	1786338	2592418
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	1786338	2592418
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-715932	-1622251
Venituri cu active imobilizate și excepționale	120		836616
Cheltuieli cu active imobilizate și excepționale	130		409025
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		427591
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-715932	-1194660
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	21207569	28773571
Cheltuieli privind impozitul pe venit	170	2588716	3487050
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	18618853	25286521

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)

BIOSISTEM.PDF

Объяснительная записка

SRL "Biosistem MLD"

Информация о соответствии финансовых отчетов национальным стандартам бухгалтерского учета

Финансовые отчеты составлены в соответствии с положениями Национальных стандартов бухгалтерского учета. Отклонения от основополагающих принципов и качественных характеристик, предусмотренных в национальных стандартах бухгалтерского учета, не были допущены.

Раскрытие учетных политик

Показатели финансовых отчетов были рассчитаны на основе методов и способов, предусмотренных в учетных политиках, утвержденных приказом директора субъекта № 3 от 30 декабря 2014 года. В течение отчетного периода в учетных политиках не было изменений.

Анализ экономико-финансовой деятельности SRL "Biosistem MLD" в 2024 году

Анализ доходов от продаж

ТАБЛИЦА АНАЛИЗА РЕНТАБЕЛЬНОСТИ АКТИВОВ. ПОКАЗАТЕЛИ

1. Общая прибыль	34683134
2. Объем продаж	72234217
3. Всего активов	68514190
4. Возвратность активов	1.05
5. Прибыльность продаж	48
6. Рентабельность активов	50.62

Величина доходов от продаж SRL "Biosistem MLD" в 2024 г. составила 72234.2 тыс. леев, что на 13342.46 тыс. леев больше, чем в предыдущем отчетном периоде. Операционная деятельность предприятия включает один вид деятельности - продажа (биохимические реактивы).

Анализ финансовых результатов и рентабельности

ТАБЛИЦА АНАЛИЗА ЭКОНОМИЧЕСКОЙ РЕНТАБЕЛЬНОСТИ ПОКАЗАТЕЛИ

1. Общая прибыль	34683134
2. Чистая прибыль	28773571
3. Собственный капитал	65745192
4. Постоянный капитал	5400
5. Уд. вес собственного капитала в постоянном капитале	1217503.5
6. Соот. общей прибыли к чистой прибыли	1.2
7. Финансовая рентабельность	43.77
8. Экономическая рентабельность	642280

В 2024 г. SRL "Biosistem MLD" получило прибыль в размере 25286.52 тыс. леев, что на 6667.67 тыс. леев больше, чем в предыдущем отчетном периоде. Это увеличение прибыли обусловлено ростом прибыли по курсовой разнице и прочих доходов.

Директор SRL "Biosistem MLD"



Poiana Vitalii.

Recipisa

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2024

Data prezentarii: 01.04.2025

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expedit pentru procesare în Sistemul Informațional al BNS : 01.04.2025 16:19:29

Recipisa 2

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2024

Data prezentarii: 01.04.2025

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 02.04.2025 16:10:17

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.

PRODUCT NAME	CODE
CLINICAL CHEMISTRY - BIOCHEMISTRY	
a-AMYLASE - DIRECT	11583
	11550
	12550
	21550
	23550
a-AMYLASE - EPS	11534
	21534
a-AMYLASE-PANCREATIC	11799
	12799
	21799
ACID PHOSPHATASE (ACP)	11548
ALANINE AMINOTRANSFERASE (ALT/GPT)	11832
	11533
	11568
	11562
	12533
	21533
	23533
ALBUMIN	11573
	11547
	12547
	21547
	23547
ALKALINE PHOSPHATASE (ALP) - AMP	11592
	11593
	11598
	12518
	21592
	23592
ALKALINE PHOSPHATASE (ALP) - DEA	11590
	11591
	11597
	12514
	21590
	23590
ASPARTATE AMINOTRANSFERASE (AST/GOT)	11830
	11531
	11567
	11561
	12531
	21531
BILIRUBIN (DIRECT)	23531
	11511
	11545
	21504

PRODUCT NAME	CODE
	23504
BILIRUBIN (TOTAL AND DIRECT)	11515
	11555
BILIRUBIN (TOTAL)	11510
	11544
	21506
	23506
CALCIUM-ARSENAZO	11570
	11571
	12570
	21570
	23570
CALCIUM-CRESOLPHTHALEIN	11811
	11812
	12513
	21511
	23511
CALCIUM-MTB	11527
	11507
CARBON DIOXIDE (CO2)	11558
	11827
	12558
	21558
CHOLESTEROL	11805
	11505
	11506
	11539
	12505
	21505
	23505
	11523
CHOLESTEROL HDL DIRECT	11557
	12557
	21557
	23557
CHOLESTEROL HDL PRECIPITATING REAGENT	11648
CHOLESTEROL LDL DIRECT	11585
	12585
	21585
	23585
CHOLESTEROL LDL PRECIPITATING REAGENT	11579
CHOLINESTERASE (CHE)	11588
	11589
	21588
CITRATE	11795
	11895
	23795
CREATINE KINASE (CK)	11790
	11791
	12524
	21790

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PRODUCT NAME	CODE
	23790
CREATINE KINASE-MB (CK-MB)	11792
	12566
	21792
	23792
CREATININE	11802
	11502
	11542
	12502
	21502
	23502
CREATININE-ENZYMATIC	11734
	12734
	21734
FRUCTOSAMINE	11046
FRUCTOSE	11794
	23794
g-GLUTAMYLTRANSFERASE (g-GT)	11584
	11520
	12520
	21520
	23520
GLUCOSE	11803
	11503
	11504
	11538
	12503
	21503
	23503
GLUCOSE-HEXOKINASE	11656
	12756
	21656
	23656
IRON- CHROMAZUROL	11546
IRON-FERROZINE	11509
	12509
	21509
	23509
LACTATE	11736
	12736
	21736
	23736
LACTATE DEHYDROGENASE (LDH)	11580
	11581
	12580
	21580
	23580
LACTATE DEHYDROGENASE (LDH) - IFCC	11586
	11587
	21586
	23586

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PRODUCT NAME	CODE
LIPASE	11793
	12793
	23793
MAGNESIUM	11797
	12797
	21797
	23797
PHOSPHORUS	11508
	12508
	21518
	23518
PROTEIN (TOTAL)	11800
	11572
	11500
	11553
	12500
	21513
	23513
PROTEIN (URINE)	11501
	11559
	12501
	21512
	23512
PYRIDOXAL PHOSPHATE	11666
TOTAL IRON BINDING CAPACITY (TIBC)	11554
TRIGLYCERIDES	11828
	11528
	11529
	12528
	21528
	23528
UNSATURATED IRON BINDING CAPACITY (UIBC)	11835
	12835
	21835
UREA/BUN - COLOR	11536
	11537
UREA/BUN - UV	11516
	11517
	11541
	12516
	21516
	23516
URIC ACID	11821
	11521
	11522
	11540
	12521
	21521
	23521
ZINC	12526
CLINICAL CHEMISTRY - TURBIDIMETRY	

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PRODUCT NAME	CODE
a1-ACID GLYCOPROTEIN	31928
	23107
ALBUMIN (MICROALBUMINURIA)	31324
	31924
	13324
	22324
	23324
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	61004
	61005
	61009
ANTI-STREPTOLYSIN O (ASO)	31323
	31923
	31031
	13923
	22923
	23923
ANTITHROMBIN III	31936
	13936
	22936
	23936
APOLIPOPROTEIN A-I (APO A-I)	31095
	23095
APOLIPOPROTEIN B (APO B)	31098
	23098
b2-MICROGLOBULIN	31925
	22925
	23925
COMPLEMENT COMPONENT C3	31073
	31079
	13084
	23103
COMPLEMENT COMPONENT C4	31074
	31080
	13085
	23104
C-REACTIVE PROTEIN (CRP)	31321
	31921
	31029
	13921
	22921
	23921
C-REACTIVE PROTEIN-hs (CRP-hs)	31927
	13927
	22927
	23927
FERRITIN	31934
	31935
	22934
	23934
	13934

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PRODUCT NAME	CODE
FIBRINOGEN	31600
	13600
	22804
	23804
FIBRINOGEN CLAUSS	61002
	61003
	61020
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)	31047
	13047
	22047
	22147
IMMUNOGLOBULIN A (IgA)	31071
	31077
	13082
	23101
IMMUNOGLOBULIN G (IgG)	31070
	31076
	13081
	23100
IMMUNOGLOBULIN M (IgM)	31072
	31078
	13083
	23102
PREALBUMIN	31929
	23106
PROTHROMBIN TIME (PT)	61001
RHEUMATOID FACTORS (RF)	31322
	31922
	31030
	13922
	22922
23922	
THROMBIN TIME (TT)	61000
TRANSFERRIN	31091
	31092
	31093
	13091
	22105
	23105
CLINICAL CHEMISTRY - MICROCOLUMN CHROMATOGRAPHY	
17-HYDROXYCORTICOSTEROIDS (17-OH)	11006
17-KETOSTEROIDS	11002
5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)	11017
5-HYDROXYINDOLEACETIC ACID (5-HIAA)	11010
HEMOGLOBIN A2	11077
METANEPHRINES	11022
VANILMANDELIC ACID	11003
CLINICAL CHEMISTRY - STANDARDS & CALIBRATORS	

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PRODUCT NAME	CODE
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	18011
AMMONIA/ETHANOL/CO2 CALIBRATOR	18065
ANTI-STREPTOLYSIN O (ASO) STANDARD	31119
APOLIPOPROTEIN A-I (APO A-I) STANDARD	31100
APOLIPOPROTEIN B (APO B) STANDARD	31200
b2-MICROGLOBULIN STANDARD	31122
BILIRUBIN STANDARD	11693
BIOCHEMISTRY CALIBRATOR	31075
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
CARBON DIOXIDE STANDARD	11822
	11833
CHOLESTEROL HDL/LDL CALIBRATOR	11824
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11750
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11603
PREALBUMIN STANDARD	31196
PROTEIN (URINE) STANDARD	31130
PROTEIN CALIBRATORS	11513
RHEUMATOID FACTORS (RF) STANDARD	31116
CLINICAL CHEMISTRY - INSTRUMENTS	
A15	83105
A25	83101
BA400	83400
BA200	83200
BTS-350	80175
CONSUMABLES (INSTRUMENTS)	
ALKALINE WASHING SOLUTION	AC17204
	AC17205
ACID WASHING SOLUTION	AC17200
	AC17201
CONCENTRATED SYSTEM LIQUID	BO11524
CONCENTRATED SYSTEM LIQUID 2	AC17206
CONCENTRATED WASHING SOLUTION	BO13416
	AC16434
Reaction Rotor	AC11485
Sample Wells (1000 units)	AC10770
WASHING SOLUTION	AC10415
	BO10771
CLINICAL CHEMISTRY - BIOCHEMISTRY - REAGENTS AUTOMATED SYSTEMS A15/A25	
ADENOSINE DEAMINASE (ADA)	12754
	23754
AMMONIA	12532
	23532

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PRODUCT NAME	CODE
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796
	21796
b-HYDROXYBUTYRATE	12525
	21525
ETHANOL	12789
	21789
HOMOCYSTEINE	12737
	21737
	23737
OXALATE	12539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551
	21551
	23551
a-1-Microglobulin	22941
C-REACTIVE PROTEIN-er (CRP-er)	22942
	23942
CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL	
ADA CONTROLS	18048
AMMONIA/ETHANOL/CO2 CONTROL I	18063
AMMONIA/ETHANOL/CO2 CONTROL II	18064
b2-MICROGLOBULIN CONTROL URINE	31215
b2-MICROGLOBULIN CONTROLS	31592
BIOCHEMISTRY CONTROL SERUM (HUMAN) I	18042
BIOCHEMISTRY CONTROL SERUM (HUMAN) II	18043
BIOCHEMISTRY CONTROL SERUM I	18009
	18005
BIOCHEMISTRY CONTROL SERUM II	18010
	18007
BIOCHEMISTRY CONTROL URINE	18054
BIOCHEMISTRY CONTROL URINE II	18066
CK-MB CONTROL SERUM	18024
CK-MB CONTROL SERUM II	18061
COAGULATION CONTROL I	61007
COAGULATION CONTROL II	61008
CONTROL URINE	18036
	18037
FERTILITY BIOCHEMISTRY CONTROL	18053
FIBRINOGEN CONTROL PLASMA	31602
FRUCTOSAMINE CONTROL SERUM	18057
HEMOGLOBIN A1C CONTROL (ELEVATED)	18002
HEMOGLOBIN A1C CONTROL (NORMAL)	18001
HEMOGLOBIN A2 CONTROL	10011
HOMOCYSTEINE CONTROL I	18058
HOMOCYSTEINE CONTROL II	18059
LIPID CONTROL SERUM I	18040
LIPID CONTROL SERUM II	18041
OXALATE CONTROL URINE	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212

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PRODUCT NAME	CODE
RHEUMATOID CONTROL SERUM I	31213
RHEUMATOID CONTROL SERUM	31214
AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE)	
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	44574
	44575
	29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148
	44548
	44715
	44557
	44710
ANTI-ISLET CELL ANTIBODIES (AICA)	44609
	44572
ANTI-KERATIN ANTIBODIES (AKA)	44618
	44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510
	44514
	44511
	44515
ANTI-nDNA ANTIBODIES (nDNA)	44825
	44818
	44817
	44820
	44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850
	44851
	44852
	44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)	44108
	44508
	44509
	44546
	44547
ANTI-NUCLEAR ANTIBODIES RL (ANA-RL)	44506
	44507
ANTI-SKIN ANTIBODIES (ASA)	44560
	44561
ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)	44520
	44524
	44521
	44525
ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)	44649
	29017
ANTI-THYROID ANTIBODIES (ATA)	44550
	44551
	29012
AUTOANTIBODIES DUO-HEp2/ML (DUO-HEp2/ML)	44874
AUTOANTIBODIES MSK/MSS (AA-MSK/MSS)	44518
AUTOANTIBODIES MSL/MSK/MSS (AA-MSL/MSK/MSS)	44826
	44827

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PRODUCT NAME	CODE
AUTOANTIBODIES-RK/RS (AA-RK/RS)	44758
	44568
AUTOANTIBODIES-RL/RK/RS (AA-RL/RK/RS)	44558
	44648
	44570
	44639
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	44588
AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS	
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549
	44893
	44732
AICA POSITIVE CONTROL	44577
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
	44891
ANA-Ce POSITIVE CONTROL	44585
ANA-Ho POSITIVE CONTROL	44502
	44890
ANA-Nu POSITIVE CONTROL	44504
ANA-Sp POSITIVE CONTROL	44503
APCA POSITIVE CONTROL	44532
ASA-bm POSITIVE CONTROL	44562
ASA-is POSITIVE CONTROL	44563
ASMA POSITIVE CONTROL	44522
	44892
AStMA POSITIVE CONTROL	44883
ATA POSITIVE CONTROL	44553
BLOTTING PAPER 12	44669
BLOTTING PAPER 4	44731
BLOTTING PAPER 6	44667
BLOTTING PAPER 8	44716
C-ANCA POSITIVE CONTROL	44854
	44912
FITC/EVANS (R)	44590
	44836
	44916
GBMA POSITIVE CONTROL	44678
GLYCIN	44846
IgA FITC/EVANS	44692
	44835
IgG FITC/EVANS	44697
	44834
IgG FITC/EVANS (M)	44847
	44882
LKM POSITIVE CONTROL	44766
MOUNTING MEDIUM	44694
nDNA POSITIVE CONTROL	44542
	44894

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PRODUCT NAME	CODE
NEGATIVE CONTROL	44696
	44889
P-ANCA POSITIVE CONTROL	44855
	44913
PBS (10x)	44592
X-ANCA POSITIVE CONTROL	44896
AUTOIMMUNITY - ELISA	
ANA-SCREENING	44785
ANTI-ANNEXIN V IgG/IgM (ANX)	44869
ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)	44868
ANTI-BPI ANTIBODIES	44905
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	44780
ANTI-CATHEPSIN G ANTIBODIES	44906
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	44865
ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	44860
ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)	44885
ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)	44884
ANTI-dsDNA ANTIBODIES	44705
ANTI-ELASTASE ANTIBODIES	44907
ANTI-GBM ANTIBODIES-EIA (GBM)	44870
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	44704
ANTI-HISTONES ANTIBODIES (HIS)	44862
ANTI-INSULIN ANTIBODIES (INS)	44873
ANTI-Jo1 ANTIBODIES	44864
ANTI-LACTOFERRIN ANTIBODIES	44908
ANTI-LYSOZYME ANTIBODIES	44909
ANTI-M2 ANTIBODIES (M2)	44871
ANTI-MPO ANTIBODIES (P-ANCA)	44790
ANTI-NUCLEOSOME ANTIBODIES (NCL)	44861
ANTI-PHOSPHOLIPID IgG/IgM (APLA)	44867
ANTI-PR3 ANTIBODIES (C-ANCA)	44791
ANTI-RIBOSOMAL P ANTIBODIES (Rib P)	44866
ANTI-Sci70 ANTIBODIES	44863
ANTI-Sm ANTIBODIES	44755
ANTI-Sm/RNP ANTIBODIES	44770
ANTI-SSA (Ro) ANTIBODIES	44765
ANTI-SS-B (La) ANTIBODIES	44750
ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)	44796
ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO)	44795
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)	44754
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)	44798
ASCA-IgG/IgA (ASCA)	44872
ENA 4-PROFILE	44775
ENA 6-PROFILE	44910
ENA 6-SCREENING	44740
AUTOIMMUNITY - INSTRUMENTS	

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PRODUCT NAME	CODE
iPRO	84101
RAPID TESTS - LATEX AGGLUTINATION	
ANTI-STREPTOLYSIN O (ASO) - SLIDE	31019
	31319
	31086
	31448
C-REACTIVE PROTEIN (CRP) - SLIDE	31011
	31311
	31012
	31107
RHEUMATOID FACTORS (RF) - SLIDE	31013
	31313
	31014
	31108
INFECTIOUS IMMUNOLOGY - SYPHILIS	
RPR-CARBON	36001
	36002
TPHA	36005
INFECTIOUS IMMUNOLOGY - FEBRILE ANTIGENS	
BRUCELLA ABORTUS	33309
BRUCELLA ABORTUS, ROSE BENGAL	33315
BRUCELLA POSITIVE CONTROL	33509
FEBRILE SERODIAGNOSTICS MULTISCREENING	33001
FEBRILE SERODIAGNOSTICS SALMONELLA	33080
	33081
PROTEUS OX19	33311
PROTEUS POSITIVE CONTROL	33502
SALMONELLA PARATYPHI AH	33301
SALMONELLA PARATYPHI AO	33302
SALMONELLA PARATYPHI BH	33303
SALMONELLA PARATYPHI BO	33304
SALMONELLA PARATYPHI CH	33305
SALMONELLA PARATYPHI CO	33306
SALMONELLA POSITIVE CONTROL	33510

P-6.1.

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





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





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		

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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:

- LS-4000 Dry Fluorescence Immunoassay Analyzer (Handheld)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019

EN ISO 18113-3:2011
EN 13641:2002

EN 13612:2002
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.

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
ISO 14971:2019

EN ISO 18113-3:2011
EN 13641:2002

EN 13612:2002
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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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

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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		

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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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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

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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:

- 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

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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:

- 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		

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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: 07/23/2024

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		

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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		

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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:

- 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		

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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:

- 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
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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:

- 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		

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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:

- 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		

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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:

- 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		

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:

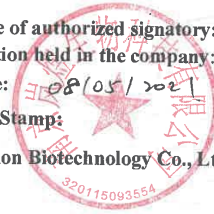
Name of authorized signatory:
Position held in the company: General Manager

Date: 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:

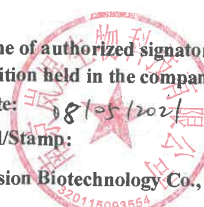
Name of authorized signatory:
Position held in the company: General Manager

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:

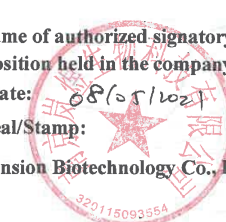
Name of authorized signatory:
Position held in the company: General Manager

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
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:

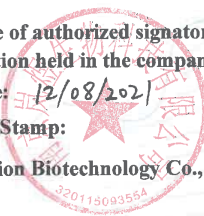
Position held in the company: General Manager

Date: 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



Declaration of Conformity

Parasep[®] Product Group (filled -with Chemical)

		Doc No.	TD002
		Version. No.	04
Declaration of Conformity		Issue Date	31 st Oct 2022
Prepared By	Sajana Vattikuti	Pages	1 of 5
Approved By	Janet Mackenzie		



EC Declaration of Conformity
European Communities Council Regulation EU 2017/746
Concerning IVD Medical Devices

Manufacturer: APACOR LIMITED
Unit 5, Sapphire Centre
Fishponds Road
Wokingham
Berkshire RG41 2QL
United Kingdom

EC Authorised Representative : Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
30175 Hannover
Germany

SRN: GB-MF-000025569 (Manufacturer)

SRN: DE-AR-000005430 (EU Authorised Representative)

We hereby declare that the following mentioned products meet the provisions of the Council Regulation EU 2017/746 covering medical devices. All documentation is controlled and retained on company premises. This declaration of conformity is issued under the sole responsibility of Apacor Limited.

Product: See list enclosed

Classification: Class A RULE 5 (C)

GMDN : 63816

UDI : Refer to the Product List enclosed

Intended Purpose: *Parasep Faecal Concentration Kit is a closed system for a clean and efficient concentration of intestinal parasites from human faecal probes. The simple 4 step kit provides a fast and simple method to concentrate helminth ova as well as protozoan cysts/ocysts. For professional in vitro diagnostic use only.*

The kits are available as reagent ready.

Standards Applied:

Document Reference	Description
BS EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
BS EN ISO 18113-2:2011	In Vitro Diagnostic Medical Devices - Information Supplied by the Manufacturer (Labelling) - Part 2: In Vitro Diagnostic Reagents for Professional Use
BS EN ISO 13485:2016+A11:2021	Medical device – Quality management system – Requirements for regulatory purposes

Declaration of Conformity		Doc No.	TD002
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Prepared By	Sajana Vattikuti	Issue Date	31st Oct 2022
Approved By	Janet Mackenzie	Pages	2 of 5

BS EN ISO 15223-1:2021	Medical Devices -- Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied -- Part 1: General Requirements
BS EN ISO 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
BS EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
MEDDEV 2.12-1 rev. 8,2013	Guidelines on a medical devices vigilance system

Notified Body N/a

Date of Issue: 31st Oct 2022

Place of Issue : Wokingham, United Kingdom.

Approved By:




Sajana Vattikuti
 QA/RA Manager
 Apacor Ltd

Change Control History

Version	Reason for change	Date
04	Addition of new product codes	31 Oct 2022
03	Addition of Manufacturers SRN and assigning of Basic UDI against each of the products	01 Jul 2022
02	Addition of UDI, Intended Use and Place of Issue	25 May 2022
01	Requirement of EN ISO 13485:2016 and IVDR EU 2017/746	10 May 2022

Declaration of Conformity		Doc No.	TD002
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Prepared By		Issue Date	31 Oct 2022
Approved By		Pages	3 of 5
Sajana Vattikuti			
Janet Mackenzie			

Product Description	Product Code	Pack Size	UDI
Mini Parasep® SF			
Mini Parasep® SF 3.3ml Apafix™	108801	40	5060170771088019F
Mini Parasep® SF 3.3ml Alcorfix™	108810	40	5060170771088109G
Mini Parasep® SF 3.3ml Formalin & Triton X	108900	40	5060170771089009J
Mini Parasep® SF 3.3ml SAF & Triton X	108920	40	5060170771089209Q
Mini Parasep® SF 3.3ml MIF & Triton X	108935	40	506017077108935A5
Mini Parasep® SF 3.3ml Bailenger + 40ml Triton X	181010	40	5060170771810109F
Mini Parasep® SF 3.3ml MIF + 40ml Triton X	181020	40	5060170771810209J
Mini Parasep® SF 3.3ml SafEFix™ Fixateur Eco	181030	40	5060170771810309M
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035	40	5060170771810359X
Mini Parasep® SF 2.4ml SafEFix™ Fixateur Eco	902500S	40	506017077902500S7J
Mini Parasep® SF 3.3ml Apafix™	108801LCD-B	40	506017077108801LCD-BNX
Mini Parasep® SF 3.3ml SafEFix™ Colour	181035LCD-B	40	506017077181035LCD-BPM
Mini Parasep® SF 8ml SafEFix™ Colour	180085LCD-B	40	506017077180085LCD-BRK
Mini Parasep®			
Mini Parasep® 2.4ml Apafix™	146003	40	50601707714600399
Mini Parasep® 2.4ml Apafix™ + 40ml Ethyl Acetate	146004	40	5060170771460049B
Mini Parasep® 2.4ml Formalin	146200	40	5060170771462009D
Mini Parasep® 2.4ml Formalin & Triton X	146300	40	5060170771463009J
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	146400	40	5060170771464009P
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Empty Bottle	146400.MI	40	506017077146400.MI4X
Mini Parasep® 2.4ml SAF & Triton X	146500	40	5060170771465009U
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	146501	40	5060170771465019W
Mini Parasep® 2.4ml Apafix™	146005	520	5060170771460059D
Mini Parasep® (Including Spoons)			
Mini Parasep® 2.4ml Formalin & Triton X + 40ml Ethyl Acetate	900000	40	5060170779000009M
Mini Parasep® 2.4ml SAF & Triton X + 40ml Ethyl Acetate	901000	40	5060170779010009U
Mini Parasep® 2.4ml Apafix™	902500	40	506017077902500AU
Mini Parasep® Stain Kit	903000	40	506017077903000AA
Midi Parasep® SF			
Midi Parasep® SF 8ml Apafix™	149901	40	506017077149901B7
Midi Parasep® SF 8ml Formalin & Triton X	149910	40	506017077149910B8
Midi Parasep® SF 8ml Alcorfix™	249300	40	506017077249300AL
Midi Parasep® SF 8ml Bailenger + 40ml Triton X	180060	40	5060170771800609P
Midi Parasep® SF 8ml MIF + 40ml Triton X	180070	40	5060170771800709S
Midi Parasep® SF 8ml SafEFix™ Ecological Fixative	180080	40	5060170771800809V
Midi Parasep® SF 8ml SafEFix™ Colour	180085	40	506017077180085A7
Midi Parasep® SF 8ml SAF & Triton X	149920	40	506017077149920BB
Midi Parasep®			
Midi Parasep® 6ml Apafix™	145002	40	5060170771450028Y
Midi Parasep® 6ml Apafix™ + 80ml Ethyl Acetate	145003	40	5060170771450039Z
Midi Parasep® 6ml Formalin	145200	40	50601707714520096
Midi Parasep® 6ml Formalin & Triton X	145300	40	5060170771453009B
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	145400	40	5060170771454009G

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Prepared By		Issue Date	31 Oct 2022
Approved By		Pages	4 of 5
Sajana Vattikuti			
Janet Mackenzie			

Midi Parasep® 6ml SAF & Triton X	145500	40	5060170771455009M
Product Description	Product Code	Pack Size	UDI
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	145501	40	5060170771455019P
Midi Parasep® 6ml Apafix	145005	180	50601707714500596
Midi Parasep® Including Spoons			
Midi Parasep® 6ml Formalin & Triton X + 80ml Ethyl Acetate	905000	40	506017077905000AQ
Midi Parasep® 6ml SAF & Triton X + 80ml Ethyl Acetate	906000	40	506017077906000AX
Midi Parasep® 6ml Apafix™	907500	40	506017077907500BX
Accessories			
Triton X-100 Solution	1472	50ml	5060170771472SY
Ethyl Acetate	1473	250ml	5060170771473T2
1:10 Triton X	172018	250ml	5060170771720189T
Triton X Solution	1499	500ml	5060170771499TL

Declaration of Conformity		Doc No.	TD002
		Version. No.	04
Prepared By Sajana Vattikuti		Issue Date	31 Oct 2022
		Pages	5 of 5
Approved By Janet Mackenzie			

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: Automatic Urinalysis System Reagent (EU-50)

Catalogue Number: 105-039227-00

Basic UDI-DI: 69449040AB760000262

Intended Purpose: It is used for diluting samples before urine analysis and preparation of cell suspension.

Classification: Class A (According to Rule 5 (a) of IVDR annex VIII)

Conformity Assessment Route: Annex II and III of IVDR

GMDN code: 55854

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2023.5.20

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2023.5.20

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

Applied Standards List

Product: Automatic Urinalysis System Reagent (EU-50)

Catalogue Number: 105-039227-00

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (EN ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices

Declaration of Conformity



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

Manufacturer SRN: CN-MF-000014156

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

Product: Urine Sediment Calibrator

Catalogue Number: 105-043513-00

Basic UDI-DI: 69449040AB760000364

Intended Purpose: Urine Sediment Calibrator is used for calibrating the applicable instruments to ensure the accuracy of measurement.

Classification: Class B (According to Rule 6 of IVDR annex VIII)

Conformity Assessment Route: Annex IX excluding CHAPTER II

GMDN code: 42064

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65
80339 München, Germany.

Notified Body No.: 0123

Identification of the Certificate: V12 044751 0190

Start of CE-Marking: 2024-1-22

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024-1-22

Signature:

A handwritten signature in black ink, appearing to read 'Wang Xinbing', is written over a dotted line.

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation Department

Declaration of Conformity V 1.0

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Urine Sediment Calibrator

Catalogue Number: 105-043513-00

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices.
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
ISO 17511: 2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
ISO 20417-2021	Medical devices — Information to be supplied by the manufacturer



Declaration of Conformity

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

Manufacturer SRN: CN-MF-000014156

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

Product: Urine Sediment Control

Catalogue Number: 105-043950-00, 105-043949-00, 105-043948-00,
105-043951-00

Basic UDI-DI: 69449040AB760000364

Intended Purpose: Urine Sediment Control is used for quality control of the applicable instruments to monitor and assess the precision of the measurement results.

Classification: Class B (According to Rule 6 of IVDR annex VIII)

Conformity Assessment Route: Annex IX excluding CHAPTER II

GMDN code: 30219

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:

Notified Body: TÜV SÜD Product Service GmbH Ridlerstraße 65
80339 München, Germany.

Notified Body No. : 0123

Identification of the Certificate: V12 044751 0190

Start of CE-Marking: 2024-1-22

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024-1-22

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation Department

Declaration of Conformity V 1.0

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Urine Sediment Control

Catalogue Number: 105-043950-00,105-043949-00,105-043948-00,105-043951-00

Standards Applied:

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements .
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices .
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 20417-2021	Medical devices — Information to be supplied by the manufacturer