MOLDOVA EUROPEANĂ

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1446048**

Din От **16.04.2026 14:46**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată "BIOSISTEM MLD"

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

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

56.68 MDL

În temeiul art. 129 pct. 13) lit. c) din Codul fiscal, suma neachitată a obligațiilor fiscale în cuantum de până la 500 de lei inclusiv nu se consideră restanță față de bugetul public național în scopul atestării lipsei restanțelor față de bugetul public național ale contribuabililor.

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **01.05.2026 14:46**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul guvernamental integrat EVO / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Интегрированный правительственный портал EVO.

Generat și semnat de Portalul guvernamental integrat EVO la **16.04.2026 14:46**

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

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

Сертификат скачен с Интегрированный правительственный портал EVO (evo.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Интегрированный правительственный портал EVO (msign.gov.md)

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

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

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

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

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

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

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

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **15.09.2023**.

Registrator în domeniul înregistrării de stat

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

Rusu Diana

EB 0461494

Date cu caracter personal

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

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

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

Lista fondatorilor Biosistem-mld SRL

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

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, bd. Moscovei, 14/1;

Scrisoare de informare

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

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

_____Vitalie Poiata

L.Ş.

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

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-20s** Including reagents as following: **M-30D DILUENT** **M-30CFL 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: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-30s** Including reagents as following: **M-30D DILUENT** **M-30CFL 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: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-20s、BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2011	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	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
IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and

Declaration of Conformity V 1.0

	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 62304:2006	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
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

BioSystems
REAGENTS & INSTRUMENTS

EC DECLARATION OF CONFORMITY

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

Hereby DECLARES

That the products stated in the annex of twelve (12) 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:

- comply 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
- are classified as Other Devices (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, 2018

Pau Vila Cases, PhD
CEO
BioSystems S.A.

www.tuv.com ID:0091006696 TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

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
	23531
BILIRUBIN (DIRECT)	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
CHOLESTEROL HDL	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

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

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	

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

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	

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 CHEMSTRY - 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

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

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 ANTBODIES (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

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

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-Scl70 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	

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

BioSystems
REAGENTS & INSTRUMENTS

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

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

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

BioSystems
Costa Brava, 30
08030 BCN

Xavier Palomar
Area Manager
27-April-2011

ISO 13485

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- LS-1100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- LS-2100 Dry Fluorescence Immunoassay Analyzer

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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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*
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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*
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Position held in the company: CTO
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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		

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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.

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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:

Place: Nanjing,China

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

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

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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*
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EN ISO 18113-2:2011		

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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.

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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:

Place: Nanjing,China

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

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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:

Place: Nanjing,China

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

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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*
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Signed on:

Place: Nanjing,China

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Position held in the company: CTO
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Seal/Stamp:
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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:

Place: Nanjing,China

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

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- SAA Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- SAA/CRP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- TT3 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- TT4 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- TSH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

In Vitro Diagnostic Directive:

- AMH Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

In Vitro Diagnostic Directive:

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

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- HbA1c Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- β -HCG Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

Lansion Biotechnology Co., Ltd.

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- LH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

320115093554

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- FSH Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

320115093554

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- PRL Test Kit (Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

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

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- BNP Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on: 25/03/2021

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- H-FABP Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on: 25/03/2021

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

In Vitro Diagnostic Directive:

- IL-6 Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on: 25/03/2021

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

In Vitro Diagnostic Directive:

- hs-cTnI Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on: 08/05/2021

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- Ferritin Test Kit(Dry Fluorescence Immunoassay)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

- PGI/PGII Test Kit(Dry Fluorescence Immunoassay)

Category:Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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

CE

DECLARATION OF CONFORMITY

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

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

European Representative: Lotus NL B.V.

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

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

In Vitro Diagnostic Directive:

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

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

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

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

Signed on:

Place: Nanjing,China

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