

ORDIN DE PLATĂ

Nr.

687

DATA EMITERII

6 ianuarie 2026

TIP.DOC.1

PLĂTIȚI:

25 000-00

LEI

Douazeci si cinci mii lei 00 bani

PLĂTITOR: (R) BIOSISTEM MLD SRL

CODUL IBAN

MD95ML00000002251429243

CODUL FISCAL

1010600028048

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP CFM Balti

CODUL IBAN

MD63ML00000002251921512

CODUL FISCAL

1003602150710

PRESTATORUL BENEFICIAR: BC'Moldindconbank'S.A.

DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achiziție publică nr. ocds-b3wdp1-MD-1766146773166 din 08.01.2026

TIPUL TRANSFERULUI
NORMAL/URGENT N

L.Ș.

CODUL TRANZACȚIEI

001

DATA PRIMIRII

DATA EXECUTĂRII

LAZAR ANNA

LAZAR ANNA

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



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ 0948048

Din
От 29.12.2025 09:48



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

BIOSISTEM MLD



**ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI
INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ 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 задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

13.01.2026 09:48



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

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **29.12.2025 09:48**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



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

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

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 |

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

Scrisoare de informare

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



Vitalie Poiata

L.Ș.

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 |
|------------|---------|----------------------|
|------------|---------|----------------------|

| | | 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).

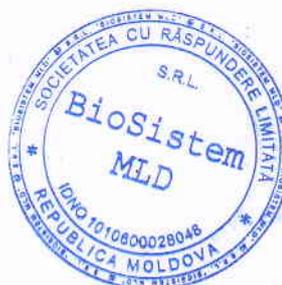
Анализ финансовых результатов и рентабельности

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 expediat 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.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

| No. | Location | Scope |
|-----|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /01 | BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain | Design, development, manufacture, distribution, installation and service of instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. |
| /02 | BIOSYSTEMS, S.A. Pol. Ind. Can Tapiolas Naves 12, 13, 21 y 22 08110 Montcada i Reixac (Barcelona) Spain | Reagent labelling and assembly. Storage of raw materials for instruments, instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. Dispatched of stored product. |

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**
Costa Brava 30
08030 Barcelona
Spain

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.
Storage of raw materials for instruments, instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched or stored product.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-12-19 until 2025-12-18.
First certification 1996

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope: Design and development, production, distribution and servicing
of instruments and reagents for clinical diagnostic.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12

J. Pyclik



Jaroslav Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

The scope of certification includes the following additional sites:

| No. | Facility | Scope |
|-----|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| /01 | BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain | Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic. |
| /02 | BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010, Montcada i Reixac – Barcelona, Spain | Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic. |

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12



J. Pyclik



Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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



Biosistem-mld SRL

Albisoara 16/1 ap.7

Chisinau, Moldova

tel.+ 373 22 808-719 / 808 - 517

fax.+ 373 22 808-519

2nd April 2021

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, manufacturer of BC-20s, BC-30s, BC-5000, BC-5150, BC-5300, BC-5310 CRP, BC-5380, BC-5390 CRP, BC-6000, BC-6200, BC-6800, BC-6800 Plus, BS-230, BS-240Pro, BS-430, BS-800, BS-2000M with relevant reagents and consumables ("**Product(s)**"), hereby certify that we authorize **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Moldova ("**You**") as our distributor to import, distribute, register, and do the Sanitary Registration of the Products in **Moldova** ("**Territory**").

This Letter of Authorization is valid from the date of issuance to **December 31, 2023**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to **You**.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the **Products**, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



Duan Liang

Sales Manager of Sales and Marketing Division, CIS
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

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



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

To: Whoever it may concern

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

04.12.2019

LETTER OF AUTHORIZATION

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

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

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

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

The Executive Manager
Adelmo Ciccioni

**BIO GROUP
MEDICAL SYSTEM SRL**
Loc. Campiano 9/B – 47867 Talamello (RN)
P.Iva / C.Fisc.: 00964170419

Otorga la presente / Grants this

ACREDITACIÓN 12/PPI020

a

BioSystems, S.A. (PREVECAL)

Según criterios recogidos en la norma UNE-EN ISO/IEC 17043, para las actividades como PROVEEDOR DE PROGRAMAS DE INTERCOMPARACIÓN definidas en el ANEXO TÉCNICO nº 12/PPI020. According to the criteria in the standard UNE-EN ISO/IEC 17043 for the Proficiency Testing Provider activities defined in the Technical Annex Nº 12/PPI020.

Fecha de entrada en vigor / Coming into effect: 26/04/2019



D. José Manuel Prieto Barrio
Presidente

La acreditación mantiene su vigencia hasta notificación en contra. Este documento no tiene validez sin su correspondiente anexo técnico. La presente acreditación y su anexo técnico están sujetos a modificaciones, suspensiones temporales y retirada. Su vigencia puede confirmarse en www.enac.es.

The accreditation maintains its validity unless otherwise stated. The present accreditation is not valid without its corresponding technical annex. This accreditation and its technical annex could be reduced, temporarily suspended and withdrawn. The state of validity of it can be confirmed at www.enac.es.

ENAC es firmante de los Acuerdos de Reconocimiento Mutuo establecidos en el seno de la European co-operation for Accreditation (EA) y de las organizaciones internacionales de organismos de acreditación, ILAC e IAF (www.enac.es)

ENAC is signatory of the Multilateral Recognition Agreements established by the European co-operation for Accreditation (EA) and the International organizations of accreditation bodies, ILAC and IAF (www.enac.es)

Ref.: CPPI/11294 Fecha de emisión 30/07/2021
El presente documento anula y sustituye al de ref. CPPI/10429

CERTIFICATO DI ACCREDITAMENTO

Accreditation Certificate

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

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

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

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

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

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

Data di 1^a emissione
1st issue date
14-11-2018

Data di modifica
Modification date
14-11-2018

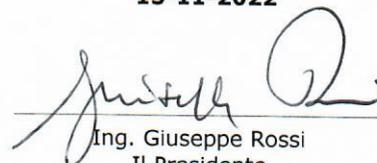
Data di scadenza
Expiring date
13-11-2022



Dott.ssa Silvia Tramontin
Il Direttore di Dipartimento
The Department Director



Dott. Filippo Trifiletti
Il Direttore Generale
The General Director



Ing. Giuseppe Rossi
Il Presidente
The President

L'accreditamento attesta la competenza tecnica dell'Organizzazione relativamente al campo di accreditamento riportato nell'Elenco Schemi allegato al presente certificato di accreditamento.

Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi, che possono variare nel tempo.

La vigenza dell'accreditamento può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure. The present certificate is valid only if associated to the annexed schedule, that may vary in the time.

Confirmation of the validity of accreditation can be verified on website www.accredia.it or by contacting the relevant Department.



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

Declaration of conformity certificate

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

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

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.

To this purpose, we guarantee and declare, on our own responsibility, what follows:

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

The present conformity declaration has validity of a maximum of 5 years.

Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.



Talamello, January the 29th, 2019

BIO GROUP
MEDICAL SYSTEM SRL
 Loc. Campiano 9/B – 47867 Talamello (RN)
 P.IVA C.Fisc. 0096170419

Cap. Soc. € 75.300,00 i.v. – Reg. Trib. Pesaro 7163 C.C.I.A.A. 98204 – P.IVA C.Fisc. 0096170419



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

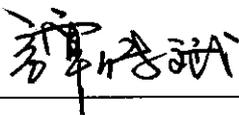
We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

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

Products: Attachment I

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

Place, Date Of Issue : Shenzhen, 2016-03-21



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

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ATTACHMENT I

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

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| | | M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control |
| Auto Hematology Analyzer | BC-5500 BC-5200 | M-50D DILUENT M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator |
| Auto Hematology Analyzer | BC-5300 BC-5100 | M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator |

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| Auto Hematology Analyzer | BC-5380 BC-5180 | M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator |
| Auto Hematology Analyzer | BC-2800 BC-2600 | M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control |
| Auto Hematology Analyzer | BC-3600、 BC-3300 BC-3300CT BC-3600CT | M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator |
| Auto Hematology Analyzer | BC-5800 BC-5600 | M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology |

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| | | Calibrator |
| Auto Hematology Analyzer | BC-6600 BC-6800 | M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator |
| Auto Hematology Analyzer | BC-5310 | M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control |
| Auto Hematology Analyzer | BC-5390 | M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control |
| Auto Hematology Analyzer | BC-5150 BC-5000 | M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator |

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| Urine Analyzer | UA-66、UA-600、 UA-600T | Urinalysis reagent strips |
| Auto Hematology Analyzer | BC-20s、BC-21s、 BC-30s、BC-31s | M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator |
| Auto Hematology Analyzer | BC-5390 CRP BC-5180 CRP | M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method) |
| Auto Sample Processing System | CAL 8000 | / |
| Auto Slide Maker & Stainer | SC-120 | M-68DS DILUENT PROBE CLEANSE |
| Automated Glycohemoglobin Analyzer | H50 H50P | Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control Hemoglobin A1c Calibrator |
| Flow Cytometer | BriCyte E6 | Sheath Fluid Cleaning Solution |
| Lysing Solution | / | / |
| CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent | / | / |
| Chemistry Analyzer | BS-300、BS-320 | ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode |

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| | | Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit |
| Chemistry Analyzer | BS-400、BS-420、 BS-480、BS-490 | ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit |
| Chemistry Analyzer | Perfect plus | ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit |

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

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| | | bottles Bar code module |
| Semi-auto Chemistry Analyzer | BA-88A | / |
| Chemistry Analyzer | BS-120、BS-130、 BS-180、BS-190 | ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module |
| Chemistry Analyzer | BS-200、BS-220 | ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module |
| Chemistry Analyzer | BS-230、BS-240 | ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode |

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| | | Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module |
| Chemistry Analyzer | BS-430、BS-450 | ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module |
| Chemistry Analyzer | BS-200E/BS-220E BS-330E/BS-350E | ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml |

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

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| | | System (RMS) |
|------------------------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chemistry Analyzer | BS-600、BS-620 | ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit |
| Chemiluminescence Immunoassay Analyzer | CL-2000i、CL-2200i | Hand-held bar code reader External vacuum pump External air pump Water supply module |
| Chemiluminescence Immunoassay Analyzer | CL-1000i | Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. Waste container |
| Chemiluminescence Immunoassay Analyzer | CL-1200i | Built-in sample bar code reader Built-in reagent bar code reader Hand-held bar code reader Reaction cuvettes. Waste container |
| α -Amylase (α -AMY) Kit (IFCC Method) | / | / |
| Aspartate Aminotransferase (AST) Kit (IFCC Method) | / | / |

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

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

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| Creatine Kinase-MB Kit(IFCC Method) | / | / |
| HDL&LDL Cholesterol Control P | / | / |
| Prealbumin Control N&P | / | / |
| Lipids Calibrator | / | / |
| Specific Proteins Calibrator | / | / |
| Multi Sera Calibrator | / | / |
| CK-MB Calibrator | / | / |
| Lipoprotein(a) Calibrator | / | / |
| Multi Control Sera N | / | / |
| Multi Control Sera P | | |
| Prealbumin Calibrator | / | / |
| Lipoprotein(a) Control N&P | / | / |
| Lipids Control N | / | / |
| Lipids Control P | | |
| CK-MB Control N | / | / |
| CK-MB Control P | | |
| Specific Proteins Control N | / | / |
| Specific Proteins Control P | | |
| Cholinesterase(CHE) Kit (DGKC Method) | / | / |
| Carbon Dioxide (CO2) Kit (Enzymic Method) | / | / |

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| Iron (Fe) Kit (Colorimetric Assay) | / | / |
| Fructosamine (FUN) Kit(Colorimetric Assay) | / | / |
| Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| Homocysteine Kit(Enzymatic Assay Method) | / | / |
| Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| Lipase Kit(Enzymatic Colorimetric Assay Method) | / | / |
| Hemoglobin A1c Kit (Enzymatic Assay Method) | / | / |
| Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method) | / | / |
| Microalbumin (MALB) Kit | / | / |
| Ferritin (FER) Kit | / | / |
| Transferrin (TRF) Kit | / | / |
| TRF Calibrator | / | / |
| TRF Control | / | / |
| FER Calibrator | / | / |
| Multimmun Control | / | / |
| MALB Calibrator | / | / |
| MALB Control | / | / |
| UIBC Control | / | / |
| UIBC Calibrator | / | / |
| α -L-Fucosidase Kit (CNPF method) | / | / |
| 5'-Nucleotidase Kit (Enzymatic Colorimetric Method) | / | / |

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| Adenosine Deaminase Kit (Enzymatic Colorimetric Method) | / | / |
| Cystatin C Kit (Turbidimetry Method) | / | / |
| β 2-Microglobulin Kit (Turbidimetry Method) | / | / |
| 5'-NT Calibrator | / | / |
| 5'-NT Control | / | / |
| ADA Control | / | / |
| ADA Calibrator | / | / |
| AFU Control | / | / |
| ASO Calibrator | / | / |
| CysC Calibrator | / | / |
| CysC Control | / | / |
| HbA1c Calibrator | / | / |
| HCY Calibrator | / | / |
| HS-CRP Calibrator | / | / |
| RF Calibrator | / | / |
| TBA Control | / | / |
| aso Calibrator | / | / |
| Free Triiodothyronine (CLIA) | / | / |
| Free Thyroxine (CLIA) | / | / |
| Total Triiodothyronine (CLIA) | / | / |
| Total Thyroxine (CLIA) | / | / |
| Thyroid-stimulating Hormone (CLIA) | / | / |
| Follicle Stimulating Hormone (CLIA) | / | / |
| Luteinizing Hormone (CLIA) | / | / |
| Prolactin (CLIA) | / | / |
| Estradiol (CLIA) | / | / |
| Estriol (CLIA) | / | / |
| Testosterone (CLIA) | / | / |
| Progesterone (CLIA) | / | / |
| Total β Human Chorionic Gonadotropin (CLIA) | / | / |

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| Free T3 Calibrators | / | / |
| Free T4 Calibrators | / | / |
| Total T3 Calibrators | / | / |
| Total T4 Calibrators | / | / |
| TSH Calibrators | / | / |
| FSH Calibrators | / | / |
| LH Calibrators | / | / |
| Prolactin Calibrators | / | / |
| Estradiol Calibrators | / | / |
| Estriol Calibrators | / | / |
| Testosterone Calibrators | / | / |
| Progesterone Calibrators | / | / |
| Total HCG Calibrators | / | / |
| Thyroid Function Multi Control | / | / |
| Reproductive Hormone Multi Control | / | / |
| Carcinoembryonic Antigen (CLIA) | / | / |
| Alpha-fetoprotein (CLIA) | / | / |
| Cancer Antigen 125 (CLIA) | / | / |
| Cancer Antigen 15-3 (CLIA) | / | / |
| Carbohydrate Antigen 19-9 (CLIA) | / | / |
| CEA Calibrators | / | / |
| AFP Calibrators | / | / |
| CA125 Calibrators | / | / |
| CA15-3 Calibrators | / | / |
| CA19-9 Calibrators | / | / |
| Ferritin Calibrators | / | / |
| Wash Buffer | / | / |
| Substrate solution | / | / |
| Antistreptolysin "O" Kit (ASO II) (Latex Immunoturbidimetric Method) | / | / |
| Antistreptolysin "O" Calibrator | / | / |
| ASO/CRP/RF Triple Control | / | / |
| Cystatin C Kit (CysC II) (Latex Immunoturbidimetric Method) | / | / |

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| Cystatin C Calibrator | / | / |
| Cystatin C Control | / | / |
| Full Range C-Reactive Protein Kit (Latex Immunoturbidimetric Method) | / | / |
| C-reactive Protein Calibrator | / | / |
| Rheumatoid Factor Kit (RF II) (Immunoturbidimetric Method) | / | / |
| Rheumatoid Factor Calibrator | / | / |
| β 2-Microglobulin Kit (β 2-MG II) (Latex Immunoturbidimetric Method) | / | / |
| β 2-Microglobulin Control | / | / |
| β 2-Microglobulin Calibrator (for Serum) | / | / |
| β 2-Microglobulin Calibrator (for Urine) | / | / |
| D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method) | / | / |
| Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method) | / | / |
| Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method) | / | / |
| β -Hydroxybutyrate (β -HB) Kit (Enzymatic Colorimetric Method) | / | / |
| High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method) | | |
| HbA1c control N | | |
| HbA1c control P | | |
| Rheumatism Control N | | |
| Rheumatism Control P | | |
| HCY Control N | | |
| HCY Control P | | |
| FUN Control P | | |
| β -2-MG Control | | |
| D-Dimer Calibrator | / | / |
| ACE Calibrator | / | / |
| RBP Calibrator | / | / |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|--------------------------------------|----------|---|
| MYO Calibrator | / | / |
| IgE Calibrator | / | / |
| β -HB Calibrator | / | / |
| D-Dimer Control | / | / |
| ACE Control | / | / |
| RBP Control | / | / |
| G6PD Control | / | / |
| β -HB Control | / | / |
| Sample Processing System | SPL 1000 | / |
| Troponin I(CLIA) | / | / |
| Troponin I Calibrators | / | / |
| B-type natriuretic peptide(CLIA) | / | / |
| BNP Calibrators | / | / |
| Myoglobin(CLIA) | / | / |
| MYO Calibrators | / | / |
| Creatine kinase MB(CLIA) | / | / |
| CK-MB Calibrators | / | / |
| Thyroglobulin(CLIA) | / | / |
| Thyroglobulin Calibrators | / | / |
| Antibody to thyroglobulin(CLIA) | / | / |
| Anti-Tg Calibrators | / | / |
| Antibody to thyroid peroxidase(CLIA) | / | / |
| Anti-TPO Calibrators | / | / |
| Insulin(CLIA) | / | / |
| Insulin Calibrators | / | / |
| C-Peptide(CLIA) | / | / |
| C-Peptide Calibrators | / | / |
| Cortisol(CLIA) | / | / |
| Cortisol Calibrators | / | / |
| Dehydroepiandrosterone sulfate(CLIA) | / | / |
| DHEA-S Calibrators | / | / |
| Adrenocorticotrophic hormone(CLIA) | / | / |
| ACTH Calibrators | / | / |

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| | | |
|---------------------------------|---|---|
| Cardiac Marker Multi Control | / | / |
| Thyroid Function Multi Control | / | / |
| Immunoassay Multi Control | / | / |
| ACTH Control | / | / |
| Anti-thyroid Antibodies Control | / | / |
| System Detection Solution | / | / |
| System Wash Solution | / | / |
| ClinChem Multi Control | / | / |
| Sample Diluent | | |

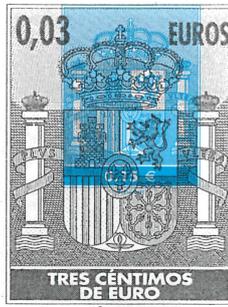
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06/2019



JOSEP PEÑARROJA FA
ADVOCATE AND SOLICITOR
COMMISSIONER FOR OATHS
OFFICIAL TRANSLATOR
GRAN VIA 594 SA 2ª
08007 BARCELONA SPAIN

CLASE 8ª



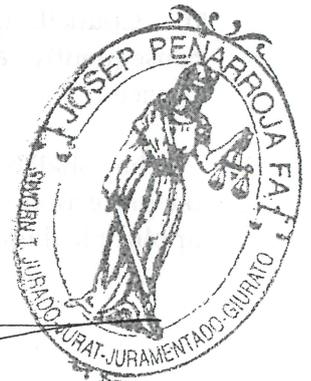
Traducción Jurada *Official translation*

Josep Peñarroja Fa
Intérprete Jurado de Inglés
Official Translator of English

Certifica que la que antecede es traducción
fiel y completa al inglés de un documento
redactado en español.

Do hereby certify that the attached translation
is a true and accurate rendering into English
of a document in Spanish.

Barcelona, - 3 MAR 2020





0N9696073



CLASE 8.ª

Traducción Jurada

[Coat of arms of Spain]

MINISTRY OF HEALTH

[Logo] Spanish Medicines and Medical Devices Agency

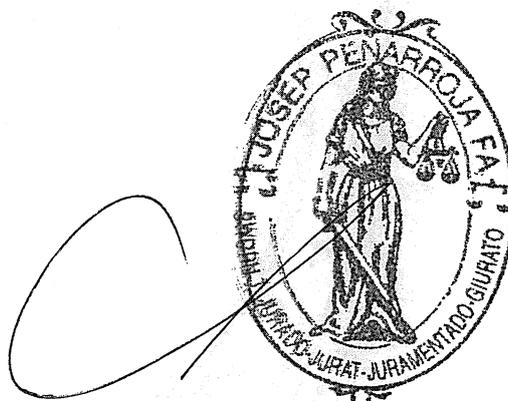
NOTIFICATION

OUR REF.: PS/DP/MFD
DATE: 19 February 2020
RE: Information to the recipient

RECIPIENT: **BIOSYSTEMS, S.A.**
C/ COSTA BRAVA, N.º 30
08030 BARCELONA (SPAIN)

With regard to the products listed below, produced by your company, considering that they are subject to external quality assessment procedures:

- PREVECAL BIOCHEMISTRY
- PREVECAL PROTEINS
- PREVECAL URINE
- PREVECAL RHEUMA
- PREVECAL BIOCHEMISTRY HUMAN
- PREVECAL ANA
- PREVECAL nDNA
- PREVECAL CELIAC
- PREVECAL ANCA
- PREVECAL COAGULATION
- PREVECAL VETERINARY



You are hereby advised that:

These products **do not** fall within the scope of Royal Decree 1662/2000, of 29 September, which transposes Directive 98/79/EC of the European Parliament and of the Council, of 27 October 1998, on in vitro diagnosis medical devices, and, consequently, are outside the sphere of competence of this Department of Medical Devices.

They shall be marketed as provided for under the general commercial laws, the laws on protection of users and consumers, and any other specific regulations which are applicable thereto.

0N98961929

06/2019



CLASE 8.^a

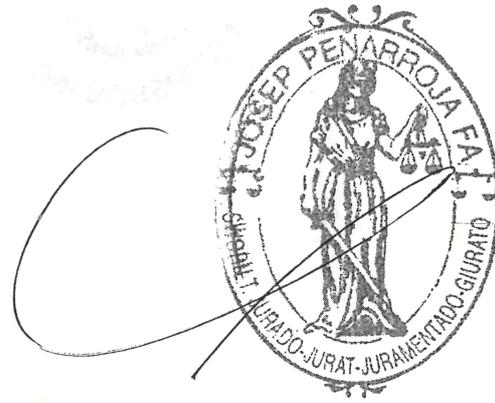
Traducción Jurada

THE HEAD OF THE DEPARTMENT
OF MEDICAL DEVICES
[Signature and seal of the Spanish Medicines
and Medical Devices Agency]
Carmen Ruiz-Villar Fernández-Bravo

E-MAIL:
mpizarro@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 09
FAX: 91 822 52 77

[There is a seal which states that the document has been recorded by the Spanish Ministry of Health, dated 20 February 2020]



T E S T I M O N I O.- ANTONIO ROSSELLÓ MESTRE, Notario del Ilustre Colegio de Cataluña, con residencia en Barcelona, -----

DOY FE: Que el presente testimonio es fiel reproducción, por fotocopia, del documento original, que me exhibe. Y para que conste libro el presente, extendido en dos folios de papel del Timbre del Estado, exclusivo para Documentos Notariales, serie FA, número el presente y el anterior correlativo en orden ascendente. -----

Barcelona a once de marzo de dos mil veinte. -----

Figura en el libro indicador con el N° 453/2020 de la Sección Segunda.-----



Antonio Roselló Mestre



Certificato Di Registrazione

Questo certificato è stato rilasciato a

Microtrace Diagnostics srl

Via Ca' di Vico 16, 47863 Novafeltria (RN) (Legal Site), Via IV Novembre 84,
47863 Novafeltria (RN) (Operative site), Italy

come riconoscimento del Sistema Gestione Qualità aziendale in conformità alle Norme

ISO 13485:2016

Le attività coperte da questo certificato sono

**Progettazione e produzione di kit diagnostici in vitro per test di
intolleranze alimentari e altri kit IVD**

Numero Del Certificato:

58429/C/0001/UK/It

Data d'emissione (originale):

13 Febbraio 2019

Data d'emissione:

13 Febbraio 2019

Emissione No:

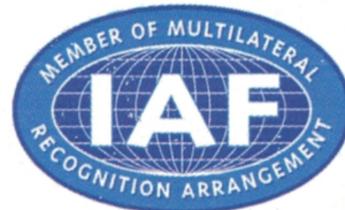
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Data di Scadenza:

12 Febbraio 2022

Emesso da:

A nome del Scheme Manager



If there is any doubt as to the authenticity of this certificate, please do not hesitate to contact the Head Office of the Group on info@urs-certification.com.
URS is a member of United Registrar of Systems (Holdings) Ltd, United House, 4 Hinton Road, Bournemouth, BH1 2EE, UK. Company Registration no. 5298466

TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



America

CERTIFICATE

No. QS6 044751 0135 Rev. 02

**Chemiluminescence Immunoassay Calibrators and Controls;
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit, Reusable
Breathing Circuit, Heat and Moisture Exchanger, Filter,
Breathing Bag**

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial
Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park
Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of
Medical Electronic Equipment (including Patient Monitor and
Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2
Cable and Temperature Cable, SPO2 Sensor, ECG Cables and
Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor,
Center Monitoring System, Telemetry Monitoring System, Pulse
Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph,
Anesthesia Machine and Accessories (Vaporizer), Ventilator,
Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology
Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate
Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay
Analyzer, Flow Cytometer, Auto Sample Processing System, Auto
Slide Maker and Stainer;) Reagents for Hematology Analyzer,
Reagents for Clinical Chemistry Analyzer, Chemiluminescence
Immunoassay Reagents, Chemiluminescence Immunoassay
Calibrators and Controls; Disposable Anesthesia Mask, Reusable
Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit,
Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter,
Breathing Bag
REPs Facility ID: F001342

Page 3 of 4

Date of Issue: 2021-07-13

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

