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ORDIN DE PLATA NR.: 63                                TIP.DOC. 1 :
                                DATA EMITERII:vineri, 31 ianuari:
=====:
PLATITI: 750-00                                LEI: Sapte Sute Cincizeci lei 00 ba :
ni                                                                    :
                                                                    :
=====:
PLATITOR: (R) 'BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" SRL                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
                                                                    :
                                                                    :
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) INSTITUTUL D                                CONTUL DE PLATI/CODUL IBAN :
E NEUROLOGIE SI NEUROCHIRURGI MD52VI022511700000034MDL :
E                                CODUL FISCAL :1003600150602 / :
                                                                    :
                                                                    :
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
B.C."VICTORIABANK"S.A.                                :VICBMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1737362357997 din 0: :
2.02.2025 : :
: :
: :
: L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:31/01/2025 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONducator:Web Poiata Vitalie :
MIIGYwYJKoZiHvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAAE Di65avx+fXSldAAAAAQOLMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzZmMzNVowXDTI0MDEyNTEyNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQOIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
                                (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZiHvcNAQcCoIIGWDCCB1QCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAAE Di65avx+fXSldAAAAAQOKMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzZmMzNVowXDTI0MDEyNTEyNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQOIEwdNb2xkb3ZhmREwDwYDVQQHEWhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
L.S.                                (semnatura electronica) :
CONducator: :
                                (semnatura manuala) :
CONTABIL-SEF: :
                                (semnatura manuala) :
SEMnatura PRESTATORUL                                L.S. :
-----:
MOTIVUL REFUZULUI : L.S. :
-----:

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GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ 1353048

Din
От 23.01.2025 13:53



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 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

07.02.2025 13:53



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 **23.01.2025 13:53**

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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

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 |

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice

Forma de proprietate: 16, Proprietate colectivă

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: +37322808719

WEB:

E-mail: zmii13@mail.ru

Numele și coordonatele al contabilului-șef: DI (dna) Tel.

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

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

la

Anexa 1

| Nr. cpt. | Indicatori | Cod rd. | Sold la | |
|----------|---|---------|---------------------------------|---------------------------------|
| | | | Începutul perioadei de gestiune | Sfârșitul perioadei de gestiune |
| 1 | 2 | 3 | 4 | 5 |
| | A C T I V | | | |
| A. | ACTIVE IMOBILIZATE | | | |
| | I. Imobilizări necorporale | | | |
| | 1. Imobilizări necorporale în curs de execuție | 010 | | |
| | 2. Imobilizări necorporale în exploatare, total | 020 | | |
| | din care: | | | |
| | 2.1. concesiuni, licențe și mărci | 021 | | |
| | 2.2. drepturi de autor și titluri de protecție | 022 | | |
| | 2.3. programe informatice | 023 | | |

| | | | |
|---|-----|---------|---------|
| 2.4. alte immobilizări necorporale | 024 | | |
| 3. Fond comercial | 030 | | |
| 4. Avansuri acordate pentru immobilizări necorporale | 040 | | |
| Total immobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040) | 050 | | |
| II. Immobilizări corporale | | | |
| 1. Immobilizări corporale în curs de execuție | 060 | | |
| 2. Terenuri | 070 | | |
| 3. Mijloace fixe, total | 080 | 3384131 | 4438372 |
| din care: | | | |
| 3.1. clădiri | 081 | | |
| 3.2. construcții speciale | 082 | | |
| 3.3. mașini, utilaje și instalații tehnice | 083 | 3363063 | 4423127 |
| 3.4. mijloace de transport | 084 | | |
| 3.5. inventar și mobilier | 085 | 21068 | 15245 |
| 3.6. alte mijloace fixe | 086 | | |
| 4. Resurse minerale | 090 | | |
| 5. Active biologice immobilizate | 100 | | |
| 6. Investiții imobiliare | 110 | | |
| 7. Avansuri acordate pentru immobilizări corporale | 120 | 5250844 | 2337159 |
| Total immobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120) | 130 | 8634975 | 6775531 |
| III. Investiții financiare pe termen lung | | | |
| 1. Investiții financiare pe termen lung în părți neafiliate | 140 | | |
| 2. Investiții financiare pe termen lung în părți afiliate, total | 150 | | |
| din care: | | | |
| 2.1. acțiuni și cote de participație deținute în părțile afiliate | 151 | | |
| 2.2. împrumuturi acordate părților afiliate | 152 | | |
| 2.3. împrumuturi acordate aferente intereselor de participare | 153 | | |
| 2.4. alte investiții financiare | 154 | | |
| Total investiții financiare pe termen lung (rd.140 + rd.150) | 160 | | |
| IV. Creanțe pe termen lung și alte active immobilizate | | | |
| 1. Creanțe comerciale pe termen lung | 170 | | |
| 2. Creanțe ale părților afiliate pe termen lung | 180 | | |
| inclusiv: creanțe aferente intereselor de participare | 181 | | |
| 3. Alte creanțe pe termen lung | 190 | | |

| | | | | |
|----|--|-----|----------|----------|
| | 4. Cheltuieli anticipate pe termen lung | 200 | | |
| | 5. Alte active imobilizate | 210 | | |
| | Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210) | 220 | | |
| | TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220) | 230 | 8634975 | 6775531 |
| B. | ACTIVE CIRCULANTE | | | |
| | I. Stocuri | | | |
| | 1. Materiale și obiecte de mică valoare și scurtă durată | 240 | 13899 | 24776 |
| | 2. Active biologice circulante | 250 | | |
| | 3. Producția în curs de execuție | 260 | | |
| | 4. Produse și mărfuri | 270 | 11123640 | 11490033 |
| | 5. Avansuri acordate pentru stocuri | 280 | | |
| | Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280) | 290 | 11137539 | 11514809 |
| | II. Creanțe curente și alte active circulante | | | |
| | 1. Creanțe comerciale curente | 300 | 4552459 | 2646694 |
| | 2. Creanțe ale părților afiliate curente | 310 | | |
| | inclusiv: creanțe aferente intereselor de participare | 311 | | |
| | 3. Creanțe ale bugetului | 320 | 27696 | 45618 |
| | 4. Creanțele ale personalului | 330 | | |
| | 5. Alte creanțe curente | 340 | | |
| | 6. Cheltuieli anticipate curente | 350 | | |
| | 7. Alte active circulante | 360 | 2268111 | 2251145 |
| | Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360) | 370 | 6848266 | 4943457 |
| | III. Investiții financiare curente | | | |
| | 1. Investiții financiare curente în părți nefiliate | 380 | | |
| | 2. Investiții financiare curente în părți afiliate, total | 390 | | |
| | din care: | | | |
| | 2.1. acțiuni și cote de participație deținute în părțile afiliate | 391 | | |
| | 2.2. împrumuturi acordate părților afiliate | 392 | | |
| | 2.3. împrumuturi acordate aferente intereselor de participare | 393 | | |
| | 2.4. alte investiții financiare în părți afiliate | 394 | | |
| | Total investiții financiare curente (rd.380 + rd.390) | 400 | | |
| | IV. Numerar și documente bănești | 410 | 10281443 | 27361722 |
| | TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410) | 420 | 28267248 | 43819988 |

| | | | | |
|----|--|-----|----------|----------|
| | TOTAL ACTIVE (rd.230 + rd.420) | 430 | 36902223 | 50595519 |
| | P A S I V | | | |
| | CAPITAL PROPRIU | | | |
| | I. Capital social și neînregistrat | | | |
| | 1. Capital social | 440 | 5400 | 5400 |
| | 2. Capital nevărsat | 450 | () | () |
| | 3. Capital neînregistrat | 460 | | |
| | 4. Capital retras | 470 | () | () |
| | 5. Patrimoniul primit de la stat cu drept de proprietate | 480 | | |
| | Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480) | 490 | 5400 | 5400 |
| | II. Prime de capital | 500 | | |
| | III. Rezerve | | | |
| | 1. Capital de rezervă | 510 | | |
| | 2. Rezerve statutare | 520 | | |
| C. | 3. Alte rezerve | 530 | | |
| | Total rezerve (rd.510 + rd.520 + rd.530) | 540 | | |
| | IV. Profit (pierdere) | | | |
| | 1. Corecții ale rezultatelor anilor precedenți | 550 | X | |
| | 2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți | 560 | 35876971 | 29813141 |
| | 3. Profit net (pierdere netă) al perioadei de gestiune | 570 | X | 18618853 |
| | 4. Profit utilizat al perioadei de gestiune | 580 | X | () |
| | Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580) | 590 | 35876971 | 48431994 |
| | V. Rezerve din reevaluare | 600 | | |
| | VI. Alte elemente de capital propriu | 610 | | |
| | TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610) | 620 | 35882371 | 48437394 |
| D. | DATORII PE TERMEN LUNG | | | |
| | 1. Credite bancare pe termen lung | 630 | | |
| | 2. Împrumuturi pe termen lung | 640 | | |
| | din care: | | | |
| | 2.1. împrumuturi din emisiunea de obligațiuni | 641 | | |
| | inclusiv: împrumuturi din emisiunea de obligațiuni convertibile | 642 | | |
| | 2.2. alte împrumuturi pe termen lung | 643 | | |
| | 3. Datorii comerciale pe termen lung | 650 | | |

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

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

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

| | | precedenta | curenta |
|--|----------|-------------------|----------------|
| 1 | 2 | 3 | 4 |
| Venituri din vânzări, total | 010 | 40621876 | 58891757 |
| din care: | | | |
| venituri din vânzarea produselor și mărfurilor | 011 | 39203671 | 57105542 |
| venituri din prestarea serviciilor și executarea lucrărilor | 012 | 1390733 | 1771148 |
| venituri din contracte de construcție | 013 | | |
| venituri din contracte de leasing | 014 | | |
| venituri din contracte de microfinanțare | 015 | | |
| alte venituri din vânzări | 016 | 27472 | 15067 |
| Costul vânzărilor, total | 020 | 22086174 | 32917436 |
| din care: | | | |
| valoarea contabilă a produselor și mărfurilor vândute | 021 | 21991682 | 32793096 |
| costul serviciilor prestate și lucrărilor executate terților | 022 | 92356 | 124340 |
| costuri aferente contractelor de construcție | 023 | | |
| costuri aferente contractelor de leasing | 024 | | |
| costuri aferente contractelor de microfinanțare | 025 | | |
| alte costuri aferente vânzărilor | 026 | 2136 | |
| Profit brut (pierdere brută) (rd.010 - rd.020) | 030 | 18535702 | 25974321 |
| Alte venituri din activitatea operațională | 040 | 128694 | 829270 |
| Cheltuieli de distribuire | 050 | 15271 | 4167 |
| Cheltuieli administrative | 060 | 3076978 | 3996115 |
| Alte cheltuieli din activitatea operațională | 070 | 1325483 | 879808 |
| Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070) | 080 | 14246664 | 21923501 |
| Venituri financiare, total | 090 | 1530710 | 1070406 |
| din care: | | | |
| venituri din interese de participare | 091 | | |
| inclusiv: veniturile obținute de la părțile afiliate | 092 | | |
| venituri din dobânzi | 093 | 250190 | 337916 |
| inclusiv: veniturile obținute de la părțile afiliate | 094 | | |
| venituri din alte investiții financiare pe termen lung | 095 | | |
| inclusiv: veniturile obținute de la părțile afiliate | 096 | | |
| venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente | 097 | | |
| venituri din ieșirea investițiilor financiare | 098 | | |
| venituri aferente diferențelor de curs valutar și de sumă | 099 | 1280520 | 732490 |

| | | | |
|---|-----|----------|----------|
| Cheltuieli financiare, total | 100 | 512939 | 1786338 |
| din care: | 101 | | |
| cheltuieli privind dobânzile | | | |
| inclusiv: cheltuielile aferente părților afiliate | 102 | | |
| cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente | 103 | | |
| cheltuieli aferente ieșirii investițiilor financiare | 104 | | |
| cheltuieli aferente diferențelor de curs valutar și de sumă | 105 | 512939 | 1786338 |
| Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100) | 110 | 1017771 | -715932 |
| Venituri cu active imobilizate și excepționale | 120 | | |
| Cheltuieli cu active imobilizate și excepționale | 130 | | |
| Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130) | 140 | | |
| Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140) | 150 | 1017771 | -715932 |
| Profit (pierdere) pînă la impozitare (rd.080 + rd.150) | 160 | 15264435 | 21207569 |
| Cheltuieli privind impozitul pe venit | 170 | 1872862 | 2588716 |
| Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170) | 180 | 13391573 | 18618853 |

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

| Nr. d/o | Indicatori | Cod rd | Sold la începutul perioadei de gestiune | Majorări | Diminuări | Sold la sfîrșitul perioadei de gestiune |
|---------|--|--------|---|----------|-----------|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| | Capital social și neînregistrat | | | | | |
| | 1. Capital social | 010 | | | | |
| | 2. Capital nevărsat | 020 | () | () | () | () |
| | 3. Capital neînregistrat | 030 | | | | |
| I. | 4. Capital retras | 040 | () | () | () | () |
| | 5. Patrimoniul primit de la stat cu drept de proprietate | 050 | | | | |
| | Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050) | 060 | | | | |
| II. | Prime de capital | 070 | | | | |
| III. | Rezerve | | | | | |
| | 1. Capital de rezervă | 080 | | | | |
| | 2. Rezerve statutare | 090 | | | | |

| | | | | | | |
|-----|---|-----|---|-----|-----|-----|
| | 3. Alte rezerve | 100 | | | | |
| | Total rezerve (rd.080 + rd.090 + rd.100) | 110 | | | | |
| | Profit (pierdere) | | | | | |
| IV. | 1. Corecții ale rezultatelor anilor precedenți | 120 | X | | | |
| | 2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți | 130 | | | | |
| | 3. Profit net (pierdere netă) al perioadei de gestiune | 140 | X | | | |
| | 4. Profit utilizat al perioadei de gestiune | 150 | X | () | () | () |
| | Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150) | 160 | | | | |
| V. | Rezerve din reevaluare | 170 | | | | |
| VI. | Alte elemente de capital propriu | 180 | | | | |
| | Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180) | 190 | | | | |

SITUAȚIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

| Indicatori | Cod rd | Perioada de gestiune | |
|---|--------|----------------------|---------|
| | | precedentă | curentă |
| 1 | 2 | 3 | 4 |
| Fluxuri de numerar din activitatea operațională | | | |
| Încasări din vânzări | 010 | | |
| Plăți pentru stocuri și servicii procurate | 020 | | |
| Plăți către angajați și organe de asigurare socială și medicală | 030 | | |
| Dobînzi plătite | 040 | | |
| Plata impozitului pe venit | 050 | | |
| Alte încasări | 060 | | |
| Alte plăți | 070 | | |
| Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070) | 080 | | |
| Fluxuri de numerar din activitatea de investiții | | | |
| Încasări din vânzarea activelor imobilizate | 090 | | |
| Plăți aferente intrărilor de active imobilizate | 100 | | |
| Dobînzi încasate | 110 | | |
| Dividende încasate | 120 | | |
| inclusiv: dividende încasate din străinătate | 121 | | |

| | | | |
|--|-----|--|--|
| Alte încasări (plăți) | 130 | | |
| Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130) | 140 | | |
| Fluxuri de numerar din activitatea financiară | | | |
| Încasări sub formă de credite și împrumuturi | 150 | | |
| Plăți aferente rambursării creditelor și împrumuturilor | 160 | | |
| Dividende plătite | 170 | | |
| inclusiv: dividende plătite nerezidenților | 171 | | |
| Încasări din operațiuni de capital | 180 | | |
| Alte încasări (plăți) | 190 | | |
| Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190) | 200 | | |
| Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200) | 210 | | |
| Diferențe de curs valutar favorabile (nefavorabile) | 220 | | |
| Sold de numerar la începutul perioadei de gestiune | 230 | | |
| Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230) | 240 | | |

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

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

Recipisa 2

Respondent

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

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

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

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



Declaration of Conformity

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

Coaguometer

(Model:CA-01, CA-02)

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

Manufactured by

CLINDIAG SYSTEMS CO., LTD

No.29 Zhiyuan Road, Jurong Economic Development Zone,

Zhenjiang, Jiangsu Province, China

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

Medical Device



May, 2018

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


.....
Authorized Signature(s)

Mr. Xu Xin

General Manager



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DECLARATION OF CONFORMITY

To whom it may concern,

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

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

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

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

Products: Attachment I

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

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

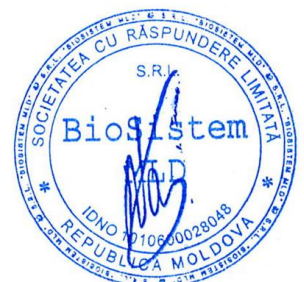
Place, Date Of Issue : Shenzhen, **2016-09-01**



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

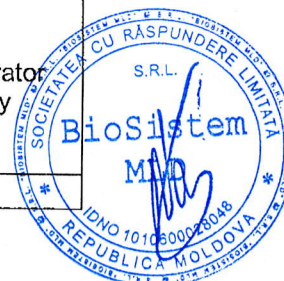
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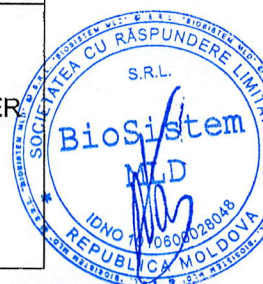
ATTACHMENT I

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



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



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



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



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



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



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



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



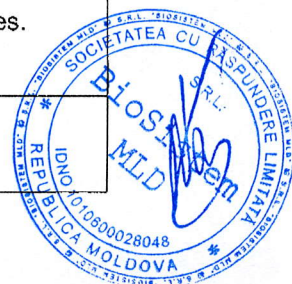
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| | | |
|--------------------|--------------------------|---|
| Chemistry Analyzer | BS-600、BS-620 | ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode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



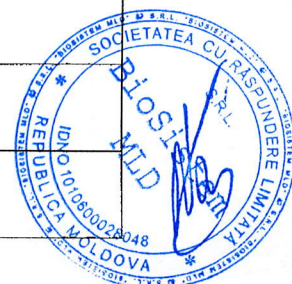
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| | | |
|--|-----------------------|--|
| | | Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction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



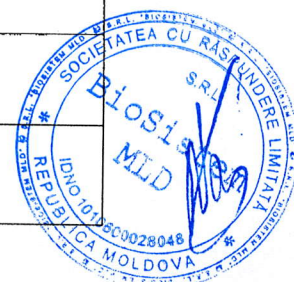
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 Keji 12th Road South, Hi-tech Industrial Park, Shenzhen
 518057, P. R. China
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| | | |
|---|---|---|
| Aspartate Aminotransferase (AST) Kit (IFCC Method) | / | / |
| Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.) | / | / |
| Lactate Dehydrogenase (LDH) Kit (IFCC Method) | / | / |
| Alanine Aminotransferase (ALT) Kit (IFCC Method) | / | / |
| C-Reactive Protein Kit(Turbidimetry Method) | / | / |
| Apolipoprotein B Kit (Turbidimetry Method) | / | / |
| Apolipoprotein A1 Kit (Turbidimetry Method) | / | / |
| Triglycerides Kit(GPO-POD Method) | / | / |
| Bilirubin Total Kit(DSA Method) | / | / |
| Creatinine Kit(Modified Jaffe Method) | / | / |
| Albumin Kit(Bromcresol Green Method) | / | / |
| Bilirubin Direct Kit(DSA Method) | / | / |
| Total Protein Kit(Biuret Method) | / | / |
| Magnesium Kit(Xylidyl Blue Method) | / | / |
| α -Hydroxybutyrate Dehydrogenase Kit(DGKC Method) | / | / |
| Total Cholesterol kit(CHOD-POD Method) | / | / |
| Alkaline Phosphatase Kit(IFCC Modified Method) | / | / |
| Urea Kit(Urease-GLDH,UV Method) | / | / |
| Uric Acid Kit(Uricase-peroxidase Method) | / | / |



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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(Turbidimetry Method) | / | / |
| Glucose Kit (HK Method) | / | / |
| Immunoglobulin A Kit(Turbidimetry Method) | / | / |
| Bilirubin Total Kit(VOX Method) | / | / |
| Creatine Kinase Kit(IFCC Method) | / | / |
| Total Bile Acids Kit(Enzymatic Cycling assay) | / | / |
| Creatinine Kit(Sarcosine Oxidase Method) | / | / |
| HDL-Cholesterol kit(Direct Method) | / | / |
| Bilirubin Direct Kit(VOX Method) | / | / |
| LDL-Cholesterol Kit(Direct Method) | / | / |
| Creatine Kinase-MB Kit(IFCC Method) | / | / |



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



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| | | |
|--|---|---|
| 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 | / | / |
| Multimun Control | / | / |
| MALB Calibrator | / | / |
| MALB Control | / | / |
| UIBC Control | / | / |
| UIBC Calibrator | / | / |
| α -L-Fucosidase Kit (CNPf method) | / | / |
| 5'-Nucleotidase Kit (Enzymatic Colorimetric Method) | / | / |
| Adenosine Deaminase Kit (Enzymatic Colorimetric Method) | / | / |
| Cystatin C Kit (Turbidimetry Method) | / | / |
| β 2-Microglobulin Kit (Turbidimetry Method) | / | / |
| 5'-NT Calibrator | / | / |
| 5'-NT Control | / | / |
| ADA Control | / | / |
| ADA Calibrator | / | / |
| AFU Control | / | / |
| ASO Calibrator | / | / |
| CysC Calibrator | / | / |



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



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| | | |
|---|---|---|
| Thyroid Function Multi Control | / | / |
| Reproductive Multi Control | / | / |
| Carcinoembryonic Antigen (CLIA) | / | / |
| Alpha-fetoprotein (CLIA) | / | / |
| Cancer Antigen 125 (CLIA) | / | / |
| Cancer Antigen 15-3 (CLIA) | / | / |
| Carbohydrate Antigen 19-9 (CLIA) | / | / |
| CEA Calibrators | / | / |
| AFP Calibrators | / | / |
| CA125 Calibrators | / | / |
| CA15-3 Calibrators | / | / |
| CA19-9 Calibrators | / | / |
| Ferritin (CLIA) | / | / |
| Ferritin Calibrators | / | / |
| Wash Buffer | / | / |
| Substrate solution | / | / |
| Antistreptolysin "O" (ASO) Kit (Latex Immunoturbidimetric Method) | / | / |
| Antistreptolysin "O" Calibrator | / | / |
| ASO/CRP/RF triple Control | / | / |
| Cystatin C (CysC) Kit (Latex Immunoturbidimetric Method) | / | / |
| Cystatin C Calibrator | / | / |
| Cystatin C Control | / | / |
| Full Range C-Reactive Protein (FR-CRP) Kit(Latex Immunoturbidimetric Method) | / | / |
| C-reactive Protein Calibrator | / | / |
| Rheumatoid Factor (RF) Kit(Immunoturbidimetric Method) | / | / |
| Rheumatoid Factor Calibrator | / | / |
| β 2-Microglobulin (β 2-MG) Kit (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) | / | / |



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| | | |
|---|----------|---|
| 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 | / | / |
| CO2 Control N | / | / |
| D-Dimer Calibrator | / | / |
| ACE Calibrator | / | / |
| RBP Calibrator | / | / |
| MYO Calibrator | / | / |
| IgE Calibrator | / | / |
| β -HB Calibrator | / | / |
| D-Dimer Control | / | / |
| ACE Control | / | / |
| RBP Control | / | / |
| G6PD Control | / | / |
| β -HB Control | / | / |
| Sample Processing System | SPL 1000 | / |
| Troponin I (CLIA) | / | / |
| Troponin I Calibrators | / | / |
| B-type natriuretic peptide (CLIA) | / | / |
| BNP Calibrators | / | / |
| Myoglobin (CLIA) | / | / |
| MYO Calibrators | / | / |



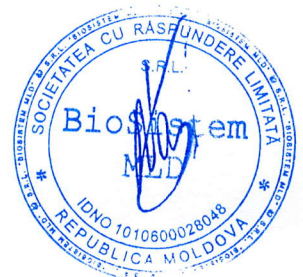
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| | | |
|--|---|---|
| Creatine kinase MB(CLIA) | / | / |
| CK-MB Calibrators | / | / |
| Thyroglobulin(CLIA) | / | / |
| Thyroglobulin Calibrators | / | / |
| Antibody to thyroglobulin(CLIA) | / | / |
| Anti-Tg Calibrators | / | / |
| Antibody to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



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





America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Certificate Holder:

**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

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

SH2405501

Effective Date:

2024-08-28

Expiry Date:

2026-06-30

Page 1 of 4

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Overall Scope Statement:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

Page 2 of 4

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

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

Facility Scopes:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

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Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

Facility(ies):

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

Facility Scopes:

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

Page 4 of 4

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



认证证书

证书号：QS5 044751 0140 Rev. 06

证书持有者：

深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦 518057

组织机构代码：

914403007084678371

认证标志：



认证范围：

证书范围见第2页

认证标准：

ISO 9001:2015

TÜV SÜD America Inc. 认证机构证明上述公司已经建立并保持满足上述所列标准要求的质量管理体系。

报告号：

SH2405501

生效期：

2024-08-28

到期时间：

2026-06-30

本证书信息可在国家认证认可监督管理委员会官方网站 (www.cnca.gov.cn) 上查询。获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

第1页共3页

日期， 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



认证证书

证书号：QS5 044751 0140 Rev. 06

认证范围：

设计和开发、生产、服务和分销：

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

深圳迈瑞生物医疗电子股份有限公司

中国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
邮编：518057

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

日期：2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



认证证书

证书号：QS5 044751 0140 Rev. 06

深圳迈瑞生物医疗电子股份有限公司
中国深圳市光明区南环大道1203号
邮编：518106

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

第3页共3页

日期， 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS



Certificate

No. Q5 044751 0164 Rev. 06

Holder of Certificate: **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

Certification Mark:



Scope of Certificate: **Design and Development, Production, Service and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_044751_0164_Rev.06

Report No.: SH2405501

Valid from: 2024-08-15

Valid until: 2026-08-31

Date, 2024-08-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 044751 0164 Rev. 06

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis,
anesthesia, breathing and intensive care; In-vitro Diagnostic
Instruments;
Non-active accessories for breathing therapy and anesthesia; In-
vitro diagnostic reagents and kits(intended) for hematology, clinical
chemistry, immunology and cell analysis (For detail information
see following pages)

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

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis,
anesthesia, breathing and intensive care; In-vitro Diagnostic
Instruments;
Non-active accessories for breathing therapy and anesthesia; In-
vitro diagnostic reagents and kits(intended) for hematology, clinical
chemistry, immunology and cell analysis (For detail information
see following pages)

Certificate

No. Q5 044751 0164 Rev. 06

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System.



认证证书

证书号: Q5 044751 0164 Rev. 06

证书持有者: 深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

认证标志:



认证范围:

设计和开发、生产、服务和分销: 有源医疗器械用于
监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备;
无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒
用于血球、临床生化、免疫及细胞分析。(具体信息范围
见附件)

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。
TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见
[www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_044751_0164_Rev_06)

报告号: SH2405501

生效期: 2024-08-15

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发证日期, 2024-08-15

Christoph Dicks

Head of Certification/Notified Body

认证证书

证书号: Q5 044751 0164 Rev. 06

认证标准:

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
医疗器械 - 质量管理体系 - 用于法规的要求

生产场地:

深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备; 无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市光明区南环大道1203号 518106

设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备; 无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

认证证书

证书号. Q5 044751 0164 Rev. 06

覆盖产品范围为:

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪），以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统