

Digitally signed by Poiata Vitalie  
Date: 2026.02.25 15:02:05 EET  
Reason: MoldSign Signature  
Location: Moldova

MOLDOVA EUROPEANĂ



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. Chișinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDMD2X329

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

## **Lista fondatorilor Biosistem-mld SRL**

| <b>Nr.</b> | <b>Nume, Prenume</b>      | <b>IDNP</b>          |
|------------|---------------------------|----------------------|
| <b>1.</b>  | <b>Vitalie Poiata</b>     | <b>0983103892591</b> |
| <b>2.</b>  | <b>Alexandr Nasedchin</b> | <b>2002001070747</b> |
| <b>3.</b>  | <b>Dmitrii Kojevnikov</b> | <b>0972305012362</b> |



## EC DECLARATION OF CONFORMITY

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

### ***Hereby DECLARES***

That the products stated in the annex of twelve (12) pages joined herewith, meet the applicable provisions of the

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2018

*P-Vila*

Pau Vila Cases, PhD  
CEO  
BioSystems S.A.



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

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

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

P.V.



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

P-21

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

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

2-4-1

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

P-411



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

25/1

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

12-5-1

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

2-51



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

24/11



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

2-2-1

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

P-6.1.

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0.04.24065

Certificate Holder: **BIOSYSTEMS S.A.**

Costa Brava 30  
08030 Barcelona  
Spain

including the branch offices 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 of 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 2025-12-19 until 2028-12-18.  
First certification 1996

2025-12-17



TÜV Rheinland Ibérica Inspection,  
Certification & Testing S.A.  
Garrotxa, 10-12 – E-08820 El Prat de  
Llobregat



**TÜVRheinland®**

[www.tuv.com](http://www.tuv.com)

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1695779-1  
Certificate Holder: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

Scope: The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.  
The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases

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.: 92837241-30  
Effective date: 2025-12-13  
Expiry date: 2028-12-12  
Issue date: 2025-11-14  
Replaces certificate SX 1695779-1 issued 2022-12-12

This certificate can be validated on <https://www.certipedia.com>

  
Daniel Świątko  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜV and TÜV are registered trademarks. Utilisation and application requires prior approval.



# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1695779-1  
Certificate Holder: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

The scope of certification also covers the following sites:

| No. | Facility                                                                                                                 | Scope                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /01 | BIOSYSTEMS S.A.<br>Costa Brava 30<br>08030 Barcelona<br>Spain                                                            | The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.<br>The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases. |
| /02 | BIOSYSTEMS S.A.<br>Polígono Industrial<br>Can Tapióles<br>Naves 12, 13, 21, 22<br>08010 Montcada i Reixac -<br>Barcelona | Labelling, assembling, warehousing and shipment of in vitro diagnostic tests kits for clinical chemistry and immunochemistry.<br>Warehousing and shipment of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.                                                                                                                                                                                                                                                                                                    |

This certificate can be validated on <https://www.certipedia.com>

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> 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 12<sup>th</sup> 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.

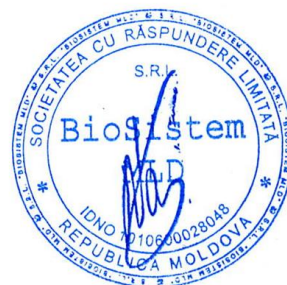
Place, Date Of Issue : Shenzhen, **2016-09-01**



**Signatory name:** Chuanbin Tan

**signatory title:** Technical Regulation Manager

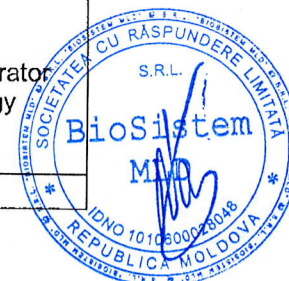
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

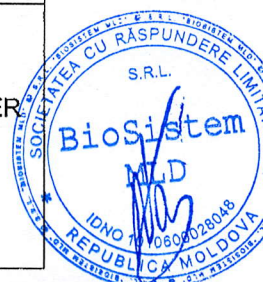
**ATTACHMENT I**

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



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

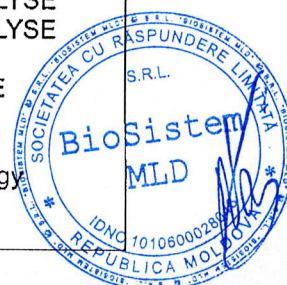
|                          |                     |                                                                                                                                                                                                                                                          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





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

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



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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

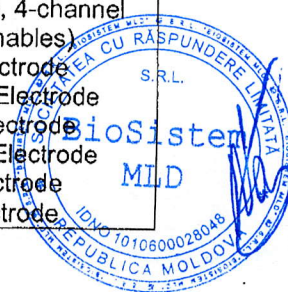


Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

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





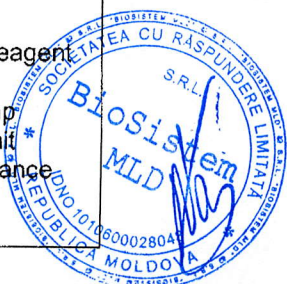
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                    |                                                                   |                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    |                                                                   | Chloride Electrode<br>Reference Electrode<br>Lithium Electrode<br>Spacer Electrode<br>Reagent Pack Na/K/Cl<br>Cleaning Solution Kit<br>Troubleshooting Kit<br>Urine Diluent, 125 ml<br>Urine Diluent, 500 ml<br>Bi-Level Quality Control<br>Kit<br>Tri-Level Quality Control<br>Kit<br>Reaction cuvette<br>Mindray reagent bottles<br>Bar code module                           |
| Microplate reader  | MR-96A                                                            | /                                                                                                                                                                                                                                                                                                                                                                               |
| Microplate washer  | MW-12A                                                            | /                                                                                                                                                                                                                                                                                                                                                                               |
| Chemistry Analyzer | BS-800、BS-820、<br>BS-800M、<br>BS-820M、<br>BS-1800、BS-1800<br>plus | ISE module<br>MR Na electrode<br>MR K electrode<br>MR Cl electrode<br>MR reference electrode<br>MR Serum Standard<br>MR Urine Standard<br>MR Urine Quality<br>Control<br>MR Buffer Solution<br>MR Detergent Solution<br>MR Na/K Check<br>Solution<br>Built-in sample/reagent<br>bar code reader<br>External Air Pump<br>Water Supply Unit<br>Remote Maintenance<br>System (RMS) |
| Chemistry Analyzer | BS-2000、<br>BS-2000M、<br>BS-2200、<br>BS-2200M                     | ISE module<br>MR Na electrode<br>MR K electrode<br>MR Cl electrode<br>MR reference electrode<br>MR Serum Standard<br>MR Urine Standard<br>MR Urine Quality<br>Control<br>MR Buffer Solution<br>MR Detergent Solution<br>MR Na/K Check<br>Solution<br>Built-in sample/reagent<br>bar code reader<br>External Air Pump<br>Water Supply Unit<br>Remote Maintenance<br>System (RMS) |



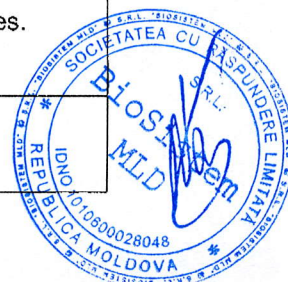
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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





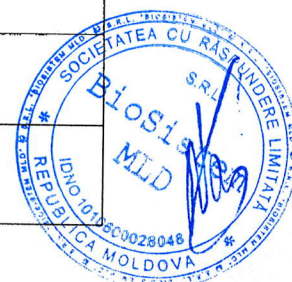
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                                                 |   |   |
|-----------------------------------------------------------------|---|---|
| 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(Bromocresol Green Method)                           | / | / |
| Bilirubin Direct Kit(DSA Method)                                | / | / |
| Total Protein Kit(Biuret Method)                                | / | / |
| Magnesium Kit(Xylidyl Blue Method)                              | / | / |
| $\alpha$ -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)                        | / | / |



**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                               |   |   |
|-----------------------------------------------|---|---|
| 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)           | / | / |



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                                                                                |   |   |
|------------------------------------------------------------------------------------------------|---|---|
| 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<br>Multi Control Sera P                                                   | / | / |
| Prealbumin Calibrator                                                                          | / | / |
| Lipoprotein(a) Control N&P                                                                     | / | / |
| Lipids Control N<br>Lipids Control P                                                           | / | / |
| CK-MB Control N<br>CK-MB Control p                                                             | / | / |
| Specific Proteins Control N Specific Proteins<br>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<br>Kit(Particle-enhanced Immunoturbidimetric Assay<br>Method | / | / |
| Homocysteine Kit(Enzymatic Assay Method)                                                       | / | / |
| Rheumatoid Factor Kit(Particle-enhanced<br>Immunoturbidimetric Assay Method)                   | / | / |



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                                                       |   |   |
|-----------------------------------------------------------------------|---|---|
| Lipase Kit(Enzymatic Colorimetric Assay Method)                       | / | / |
| Hemoglobin A1c Kit (Enzymatic Assay Method)                           | / | / |
| Unsaturated Iron Binding Capacity (UIBC) Kit<br>(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                                                       | / | / |
| $\alpha$ -L-Fucosidase Kit (CNPF method)                              | / | / |
| 5'-Nucleotidase Kit (Enzymatic Colorimetric<br>Method)                | / | / |
| Adenosine Deaminase Kit (Enzymatic<br>Colorimetric Method)            | / | / |
| Cystatin C Kit (Turbidimetry Method)                                  | / | / |
| $\beta$ 2-Microglobulin Kit (Turbidimetry Method)                     | / | / |
| 5'-NT Calibrator                                                      | / | / |
| 5'-NT Control                                                         | / | / |
| ADA Control                                                           | / | / |
| ADA Calibrator                                                        | / | / |
| AFU Control                                                           | / | / |
| ASO Calibrator                                                        | / | / |
| CysC Calibrator                                                       | / | / |





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                                   |   |   |
|---------------------------------------------------|---|---|
| CysC Control                                      | / | / |
| HbA1c Calibrator                                  | / | / |
| HCY Calibrator                                    | / | / |
| HS-CRP Calibrator                                 | / | / |
| RF Calibrator                                     | / | / |
| TBA Control                                       | / | / |
| $\beta$ 2-MG Calibrator                           | / | / |
| $\beta$ 2-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 $\beta$ 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 $\beta$ HCG Calibrators                     | / | / |



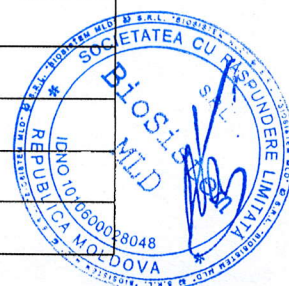
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

|                                                                                   |   |   |
|-----------------------------------------------------------------------------------|---|---|
| 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<br>(Latex Immunoturbidimetric Method)              | / | / |
| Antistreptolysin "O" Calibrator                                                   | / | / |
| ASO/CRP/RF triple Control                                                         | / | / |
| Cystatin C (CysC) Kit (Latex Immunoturbidimetric<br>Method)                       | / | / |
| Cystatin C Calibrator                                                             | / | / |
| Cystatin C Control                                                                | / | / |
| Full Range C-Reactive Protein (FR-CRP)<br>Kit(Latex Immunoturbidimetric Method)   | / | / |
| C-reactive Protein Calibrator                                                     | / | / |
| Rheumatoid Factor (RF) Kit(Immunoturbidimetric<br>Method)                         | / | / |
| Rheumatoid Factor Calibrator                                                      | / | / |
| $\beta$ 2-Microglobulin ( $\beta$ 2-MG) Kit<br>(Latex Immunoturbidimetric Method) | / | / |
| $\beta$ 2-Microglobulin Control                                                   | / | / |
| $\beta$ 2-Microglobulin Calibrator (for Serum)                                    | / | / |
| $\beta$ 2-Microglobulin Calibrator (for Urine)                                    | / | / |
| D-Dimer kit (Particle-enhanced<br>Immunoturbidimetric Assay Method)               | / | / |
| Angiotensin Converting Enzyme (ACE) Kit<br>(Enzymatic Colorimetric Assay Method)  | / | / |



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

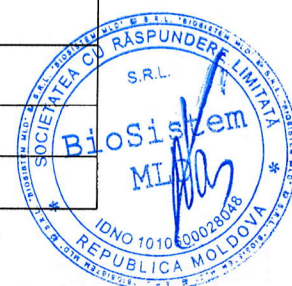
|                                                                                                 |          |   |
|-------------------------------------------------------------------------------------------------|----------|---|
| Retinol Binding Protein (RBP) Kit<br>(Particle-enhanced Immunoturbidimetric Assay Method)       | /        | / |
| Glucose-6-Phosphate Dehydrogenase (G6PD) Kit<br>(UV Enzymatic Method)                           | /        | / |
| Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)                        | /        | / |
| Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)                 | /        | / |
| $\beta$ -Hydroxybutyrate ( $\beta$ -HB) Kit (Enzymatic Colorimetric Method)                     | /        | / |
| High Sensitivity C-reaction Protein Kit<br>(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                                                                                  | /        | / |
| $\beta$ -HB Calibrator                                                                          | /        | / |
| D-Dimer Control                                                                                 | /        | / |
| ACE Control                                                                                     | /        | / |
| RBP Control                                                                                     | /        | / |
| G6PD Control                                                                                    | /        | / |
| $\beta$ -HB Control                                                                             | /        | / |
| Sample Processing System                                                                        | SPL 1000 | / |
| Troponin I (CLIA)                                                                               | /        | / |
| Troponin I Calibrators                                                                          | /        | / |
| B-type natriuretic peptide (CLIA)                                                               | /        | / |
| BNP Calibrators                                                                                 | /        | / |
| Myoglobin (CLIA)                                                                                | /        | / |
| MYO Calibrators                                                                                 | /        | / |





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

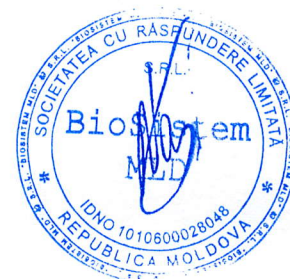
|                                                                        |   |   |
|------------------------------------------------------------------------|---|---|
| Creatine kinase MB(CLIA)                                               | / | / |
| CK-MB Calibrators                                                      | / | / |
| 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                                                       | / | / |
| 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)                                           | / | / |





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

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





# 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

Page 3 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.**

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](http://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





America

# 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





America

# 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、尿液分析仪用试剂、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



Product Service

# 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](http://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

有效期: 2026-08-31

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