

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2501358**

din  
от **06.02.2025**

**1. Destinația / Назначение**

Pentru participarea la proceduri de achiziții publice

**2. Date despre contribuabil / Информация о налогоплательщике**

|  |   |
|--|---|
| <b>Denumirea</b><br>Наименование   | <b>Codul fiscal / Numărul de identificare</b><br>Фискальный код / Идентификационный номер |
| <b>BIOSISTEM MLD S.R.L.</b>  | 1010600028048   |
| <b>Adresa sediului de bază (strada, numărul)</b><br>Адрес основного месторасположения (улица, номер) | <b>Codul - Denumirea localității</b><br>Код - Наименование населенного пункта             |
| Albisoara nr.16 bl.1 of.7  | 0150-SEC.RISCANI  |

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /**  
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:  
**0,00 lei/лей.**

**4. Valabil pînă la / Действителен до 21.02.2025**

**5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы**

Șefă DDF Rîșcani

Funcția/Должность

Semnătura/Подпись

CĂUȘ Viorica

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **GOJAN Claudia**  
Numele și prenumele/Фамилия и имя

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

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

*Numărul de identificare de stat - codul fiscal*  
**1010600028048**

*Data înregistrării*

**12.08.2010**

*Data eliberării*

**12.08.2010**

**Svirepova Ludmila, registrator**

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

*L. Svirepova*  
semnătura

MD 0101250





## AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

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

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

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

**Registrator în domeniul  
înregistrării de stat**

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



**Rusu Diana**



**EB 0461494**



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

Republica Moldova, MD-2068  
mun. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDDMD2X329

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

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московей, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDDMD2X329

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 MOLDDMD2X329.

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> |

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.

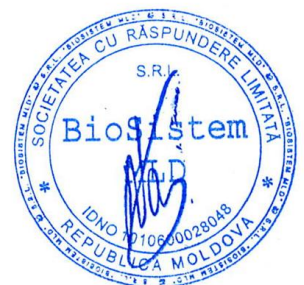
Place, Date Of Issue : Shenzhen, 2016-09-01



**Signatory name:** Chuanbin Tan

**signatory title:** Technical Regulation Manager

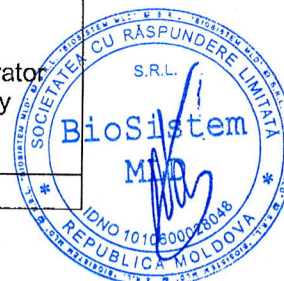
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**



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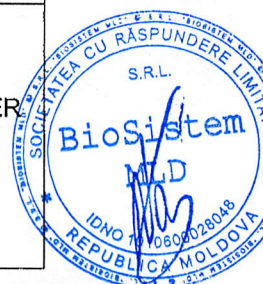
**ATTACHMENT I**

| 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   |



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





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



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



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|  |                               |  |
|--|-------------------------------|--|
|  |                               | 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<br>CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC<br>Reagent<br>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 cuvettes |

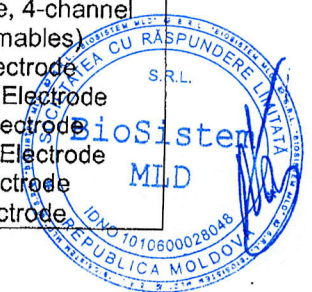


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|                    |               |   |
|--------------------|---------------|---|
|                    |               | Mindray reagent bottles<br>Bar code module<br>Drainage unit<br>Water supply unit  |
| Chemistry Analyzer | Perfect plus  | 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 Kit<br>Tri-Level Quality Control 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 Kit<br>Tri-Level Quality Control 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  |



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|                              |                                    |   |
|------------------------------|------------------------------------|---|
|                              |                                    | 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、<br>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  |



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|                    |   |   |
|--------------------|---|---|
|                    |   | 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                     |
| 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 Control<br>MR Buffer Solution<br>MR Detergent Solution<br>MR Na/K Check Solution<br>Built-in sample/reagent bar code reader<br>External Air Pump<br>Water Supply Unit<br>Remote Maintenance 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 Control<br>MR Buffer Solution<br>MR Detergent Solution<br>MR Na/K Check Solution<br>Built-in sample/reagent bar code reader<br>External Air Pump<br>Water Supply Unit<br>Remote Maintenance System (RMS) |



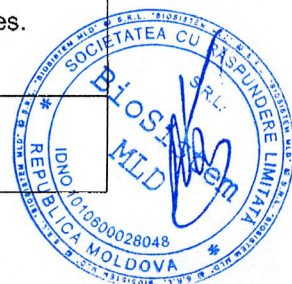
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|                    |                          |   |
|--------------------|--------------------------|---|
| Chemistry Analyzer | BS-600、BS-620            | ISE Module, 4-channel<br>(No consumables)<br>Sodium Electrode<br>Potassium Electrode<br>Chloride 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  |



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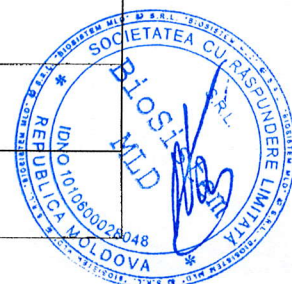
|  |                       |  |
|--|-----------------------|--|
|  |                       | Spacer Electrode<br>Reagent Pack Na/K/Cl<br>Cleaning Solution Kit<br>Troubleshooting Kit<br>Urine Diluent, 125 ml<br>Urine Diluent, 500 ml<br>Bi-Level Quality Control<br>Kit<br>Tri-Level Quality Control<br>Kit<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) | /                     | /  |





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|   |   |   |
|---|---|---|
| Aspartate Aminotransferase (AST) Kit (IFCC Method)              | / | / |
| Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.) | / | / |
| Lactate Dehydrogenase (LDH) Kit (IFCC Method)                   | / | / |
| Alanine Aminotransferase (ALT) Kit (IFCC Method)                | / | / |
| C-Reactive Protein Kit(Turbidimetry Method)                     | / | / |
| Apolipoprotein B Kit (Turbidimetry Method)                      | / | / |
| Apolipoprotein A1 Kit (Turbidimetry Method)                     | / | / |
| Triglycerides Kit(GPO-POD Method)                               | / | / |
| Bilirubin Total Kit(DSA Method)                                 | / | / |
| Creatinine Kit(Modified Jaffe Method)                           | / | / |
| Albumin Kit(Bromcresol Green Method)                            | / | / |
| Bilirubin Direct Kit(DSA Method)                                | / | / |
| Total Protein Kit(Biuret Method)                                | / | / |
| Magnesium Kit(Xylidyl Blue Method)                              | / | / |
| $\alpha$ -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)                        | / | / |



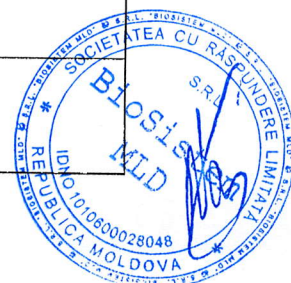
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|   |   |   |
|---|---|---|
| Glucose Kit (GOD-POD Method)                  | / | / |
| Phosphorus Kit(Phosphomolybdate Method)       | / | / |
| Calcium Kit(Arsenazo III Method)              | / | / |
| Lipoprotein(a) Kit(Turbidimetry Method)    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



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



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|--|---|---|
| Lipase Kit(Enzymatic Colorimetric Assay Method)                    | / | / |
| Hemoglobin A1c Kit (Enzymatic Assay Method)                        | / | / |
| Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method) | / | / |
| Microalbumin (MALB) Kit  | / | / |
| Ferritin (FER) Kit   | / | / |
| Transferrin (TRF) Kit  | / | / |
| TRF Calibrator   | / | / |
| TRF Control  | / | / |
| FER Calibrator   | / | / |
| Multimun Control   | / | / |
| MALB Calibrator  | / | / |
| MALB Control   | / | / |
| UIBC Control   | / | / |
| UIBC Calibrator  | / | / |
| $\alpha$ -L-Fucosidase Kit (CNPF method)                           | / | / |
| 5'-Nucleotidase Kit (Enzymatic Colorimetric Method)                | / | / |
| Adenosine Deaminase Kit (Enzymatic 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  | / | / |



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



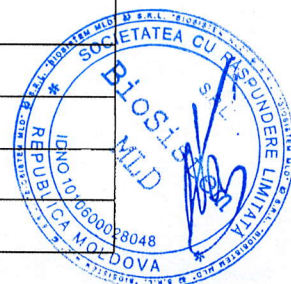
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|   |   |   |
|---|---|---|
| Thyroid Function Multi Control  | / | / |
| Reproductive Multi Control  | / | / |
| Carcinoembryonic Antigen (CLIA)   | / | / |
| Alpha-fetoprotein (CLIA)  | / | / |
| Cancer Antigen 125 (CLIA)   | / | / |
| Cancer Antigen 15-3 (CLIA)  | / | / |
| Carbohydrate Antigen 19-9 (CLIA)  | / | / |
| CEA Calibrators   | / | / |
| AFP Calibrators   | / | / |
| CA125 Calibrators   | / | / |
| CA15-3 Calibrators  | / | / |
| CA19-9 Calibrators  | / | / |
| Ferritin (CLIA)   | / | / |
| Ferritin Calibrators  | / | / |
| Wash Buffer   | / | / |
| Substrate solution  | / | / |
| Antistreptolysin "O" (ASO) Kit<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)  | / | / |



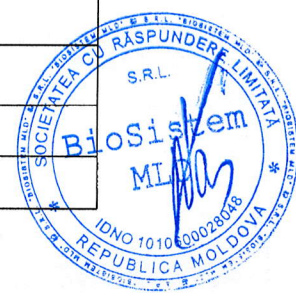
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|---|----------|---|
| Retinol Binding Protein (RBP) Kit<br>(Particle-enhanced Immunoturbidimetric Assay Method)       | /        | / |
| Glucose-6-Phosphate Dehydrogenase (G6PD) Kit<br>(UV Enzymatic Method)                           | /        | / |
| 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   | /        | / |



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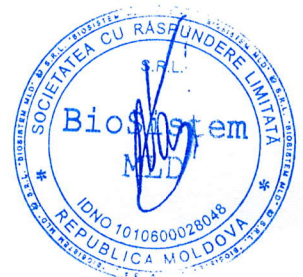
|  |   |   |
|--|---|---|
| Creatine kinase MB(CLIA)   | / | / |
| CK-MB Calibrators  | / | / |
| Thyroglobulin(CLIA)  | / | / |
| Thyroglobulin Calibrators  | / | / |
| Antibody to thyroglobulin(CLIA)  | / | / |
| Anti-Tg Calibrators  | / | / |
| Antibody to thyroid peroxidase(CLIA)                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





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



## 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 five (5) 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:

- complies 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
- is classified as Other Device (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 6<sup>th</sup>, 2012


Dr. Antonio Elduque  
Managing director  
BioSystems S.A.



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



## **CLINICAL CHEMISTRY – BIOCHEMISTRY:**

|                                       |                                    |
|---------------------------------------|------------------------------------|
| a-Amylase-Direct                      | Creatine Kinase (CK)               |
| a-Amylase-EPS                         | Creatine Kinase-MB (CK-MB)         |
| a-Amylase-Pancreatic                  | Creatinine                         |
| Acid Phosphatase (ACP)                | Fructosamine                       |
| Alanine Aminotransferase (ALT/GPT)    | Fructose                           |
| Albumin                               | g-Glutamyltransferase (g-GT)       |
| Alkaline Phosphatase (ALP)-AMP        | Glucose                            |
| Alkaline Phosphatase (ALP)-DEA        | Iron – Chromazurol                 |
| AspartateAminotranferase (AST/GOT)    | Iron – Ferrozine                   |
| Bilirubin (direct)                    | Iron Binding Capacity              |
| Bilirubin (total and direct)          | Lactate Dehydrogenase (LDH)        |
| Bilirubin (total)                     | Lactate Dehydrogenase (LDH) – IFCC |
| Calcium – Arsenazo                    | Lipase                             |
| Calcium – MTB                         | Magnesium                          |
| Cholesterol                           | Phosphorus                         |
| Cholesterol HDL                       | Protein (total)                    |
| Cholesterol HDL direct                | Protein (urine)                    |
| Cholesterol HDL Precipitating reagent | Pyridoxal Phosphate                |
| Cholesterol LDL direct                | Triglycerides                      |
| Cholesterol LDL Precipitating reagent | Urea/BUN-Color                     |
| Cholinesterase (CHE)                  | Urea/BUN-UV                        |
| Citrate                               | Uric Acid                          |

## **CLINICAL CHEMISTRY – TURBIDIMETRY:**

|                              |                                |
|------------------------------|--------------------------------|
| a1-acid Glycoprotein         | C-Reactive Protein (CRP)       |
| Albumin (Microalbuminuria)   | C-Reactive Protein-hs (CRP-hs) |
| Anti-Streptolysin O (ASO)    | Ferritin                       |
| Antithrombin III             | Immunoglobulin A (IgA)         |
| Apolipoprotein A-I (Apo A-I) | Immunoglobulin G (IgG)         |
| Apolipoprotein B (Apo B)     | Immunoglobulin M (IgM)         |
| b2-Microglobulin             | Prealbumin                     |
| Complement Component C3      | Rheumatoid Factors (RF)        |
| Complement Component C4      | Transferrin                    |

## **CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:**

|  |                    |
|--|--------------------|
| 17-Hydroxycorticosteroids                              | Hemoglobin A1C     |
| 17-Ketosteroids  | Hemoglobin A2      |
| 5-Aminolevulinic Acid (ALA) /<br>Porphobilinogen (PBG) | Metanephrines      |
| 5-Hydroxyindoleacetic acid (5-HIAA)                    | Vanilmandelic Acid |



## **CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:**

|                                     |   |
|-------------------------------------|---|
| a-1-acid Glycoprotein Standard      | Biochemistry Calibrator (Human)             |
| Adenosine Deaminase (ADA) Standard  | Cholesterol HDL/LDL Calibrator              |
| Albumin (Microalbuminuria) Standard | CRP/CRP-hs Standard                         |
| Anti-Streptolysin O (ASO) Standard  | Ferritin Standard                           |
| Antithrombin III Standard           | Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard |
| Apolipoprotein A-I Standard         | Prealbumin Standard                         |
| Apolipoprotein B Standard           | Protein Calibrators                         |
| b2-Microglobulin Standard           | Protein (urine) Standard                    |
| Bilirubin Standard                  | Rheumatoid Factors (RF) Standard            |
| Biochemistry Calibrator             |   |

## **CLINICAL CHEMISTRY – INSTRUMENTS:**

|     |         |
|-----|---------|
| A15 | BA400   |
| A25 | BTS-350 |

## **CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:**

|                                      |                              |
|--------------------------------------|------------------------------|
| a-Amylase-Direct                     | Creatine Kinase (CK)         |
| a-Amylase-Pancreatic                 | Creatine Kinase-MB (CK-MB)   |
| Adenosine Deaminase (ADA)            | Creatinine                   |
| Alanine Aminotransferase (ALT/GPT)   | g-Glutamyltransferase (g-GT) |
| Albumin                              | Glucose                      |
| Alkaline Phosphatase (ALP)-AMP       | Iron Ferrozine               |
| Alkaline Phosphatase (ALP)-DEA       | Lactate dehydrogenase (LDH)  |
| Aspartate Aminotransferase (AST/GOT) | Lipase                       |
| Bilirubin (direct)                   | Magnesium                    |
| Bilirubin (total)                    | Phosphorus                   |
| Calcium-Arsenazo                     | Protein (total)              |
| Cholesterol                          | Protein (urine)              |
| Cholesterol HDL direct               | Triglycerides                |
| Cholesterol LDL direct               | Urea/BUN UV                  |
|                                      | Uric acid                    |



## **CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:**

|                                |                                    |
|--------------------------------|------------------------------------|
| Albumin (Microalbuminuria)     | Ferritin                           |
| Anti-Streptolysin O (ASO)      | Hemoglobin A1C-Turbi (HbA1C-Turbi) |
| Antithrombin III               | Immunoglobulin A (IgA)             |
| Complement Component C3        | Immunoglobulin G (IgG)             |
| Complement Component C4        | Immunoglobulin M (IgM)             |
| C-Reactive Protein (CRP)       | Rheumatoid Factors (RF)            |
| C-Reactive Protein-hs (CRP-hs) | Transferrin                        |

## **CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:**

|                                       |                                 |
|---------------------------------------|---------------------------------|
| ADA Controls                          | Hemoglobin A1C Control (Normal) |
| Biochemistry Control Serum (Human) I  | Hemoglobin A2 Control           |
| Biochemistry Control Serum (Human) II | Lipid Control Serum I           |
| Biochemistry Control Serum I          | Lipid Control Serum II          |
| Biochemistry Control Serum II         | Protein Control Serum I         |
| CK-MB Control Serum                   | Protein Control Serum II        |
| Control Urine                         | Rheumatoid Control Serum I      |
| Fertility Biochemistry Control        | Rheumatoid Control Serum II     |
| Hemoglobin A1C Control (Elevated)     |                                 |

## **AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):**

|   |  |
|---|--|
| Anti-Adrenal Cortex Antibodies (AACCA)        | Anti-Thyroid Antibodies (ATA)                  |
| Anti-Endomysium Antibodies (AEA)              | Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)       |
| Anti-Islet Cell Antibodies (AICA)             | Autoantibodies MsK/MsS (AA-MsK/MsS)            |
| Anti-Keratin Antibodies (AKA)                 | Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)    |
| Anti-Mitochondrial Antibodies (AMA)           | Autoantibodies RK/RS (AA-RK/RS)                |
| Anti-nDNA antibodies (nDNA)                   | Autoantibodies RL/RK/RS (AA-RL/RK/RS)          |
| Anti-Neutrophil Cytoplasmic Antibodies (ANCA) | Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)        |
| Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)     | Glomerular Basement Membrane Antibodies (GBMA) |
| Anti-Nuclear Antibodies RL (ANA-RL)           |  |
| Anti-Skin Antibodies (ASA)                    |  |
| Anti-Smooth Muscle Antibodies (ASMA)          |  |
| Anti-Striated Muscle Antibodies (AStMA)       |  |



## ***AUTOIMMUNITY – ELISA:***

ANA Screening  
Anti-Annexin V IgG/IgM (ANX)  
Anti-b2-Glycoprotein 1 IgG/IgM  
(b2GP1)  
Anti-Cardiolipin Antibodies (ACA-  
IgG/IgM)  
Anti-Centromere B Antibodies (CENP-  
B)  
Anti-Citrullinated Protein Antibodies  
(ACPA)  
Anti-Deamidated Gliadin Peptides IgA  
(DGP IgA)  
Anti-Deamidated Gliadin Peptides IgG  
(DGP IgG)  
Anti-dsDNA Antibodies  
Anti-GBM Antibodies - EIA (GBM)  
Anti-Gliadin Antibodies (AGA-IgG/IgA)  
Anti-Histones Antibodies (HIST)  
Anti-Insulin Antibodies (INS)  
Anti-Jo1 Antibodies  
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies  
Anti-Nucleosome Antibodies (NCL)  
Anti-Phospholipid IgG/IgM (APLA)  
Anti-PR3 Antibodies  
Anti-Ribosomal P Antibodies (Rib P)  
Anti-Scl70 Antibodies  
Anti-Sm Antibodies  
Anti-Sm/RNP Antibodies  
Anti-SSA (Ro) Antibodies  
Anti-SSB (La) Antibodies  
Anti-Thyroglobulin Antibodies (Anti-Tg)  
Anti-Thyroid Peroxidase Antibodies  
(Anti-TPO)  
Anti-tTransglutaminase IgA Antibodies  
(Anti- tTG IgA)  
Anti-tTransglutaminase IgG Antibodies  
(Anti- tTG IgG)  
ASCA-IgG/IgA (ASCA)  
ENA 4-Profile  
ENA 6-Screening

## ***AUTOINMUNIDAD – INSTRUMENTOS:***

## ***AUTOIMMUNITY – INSTRUMENTS:***

iPRO



### ***RAPID TESTS – LATEX AGGLUTINATION:***

Anti-Streptolysin O (ASO) - Slide  
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

### ***INFECTIOUS IMMUNOLOGY – SYPHILIS:***

RPR-Carbon

TPHA

### ***INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:***

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

# Declaration of Conformity **CE**

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

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

**Product:** Auto Hematology Analyzer  
**Model:** BC-3600

Including reagents as following:

**M-30D DILUENT**  
**M-30CFL LYSE**  
**M-30R RINSE**  
**PROBE CLEANSER**

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

**Conformity Assessment Route:** IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the  
provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical  
Devices. All supporting documentations are retained under the premises  
of the manufacturer.

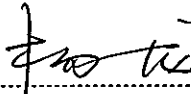
**Standards Applied:**

List of (harmonized) standards for which documented evidence for compliance can be  
provided as attachment.

**Start of CE-Marking:** 2011-01-14

**Place, Date of Issue:** Shenzhen, 2011-01-14

**Signature:**



**Name of Authorized Signatory:** Mr. Yang Long

**Position Held in Company:** Management Representative





# Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

**Manufacturer:** Dirui Industrial Co., Ltd.  
95 Yunhe Street New& High Tech. Development Zone  
Changchun Jilin 130012 P.R. China

**Authorized Representative:** Emergo Europe

Molenstraat 15 2513 BH The Hague  
The Netherlands

**Medical Device :** Product Name: Reagent strips for Urinalysis

IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture  
(where applicable)

- DIRUI 1 ITEMS (GLU)      DIRUI 1 ITEMS (KET)      DIRUI 1 ITEMS (PRO)
- DIRUI 2 ITEMS (PRO, GLU)      DIRUI 2 ITEMS (KET, GLU)
- DIRUI 3 ITEMS (PRO, PH, GLU)      DIRUI 3 ITEMS (PRO, KET, GLU)
- DIRUI 4 ITEMS (PRO, PH, BLD, GLU)      DIRUI 4 ITEMS (PRO, PH, SG, GLU)
- DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU)
- DIRUI 8 ITEMS      DIRUI H8
- DIRUI 9 ITEMS
- DIRUI A10    DIRUI H10    DIRUI E10    DIRUI M10    DIRUI H10-800
- DIRUI H11    DIRUI H11-MA    DIRUI H11-800
- DIRUI H11-800MA      DIRUI H12-800MA
- DIRUI H13-Cr      DIRUI H14-Ca
- DIRUI H13-Cr (H-800)      DIRUI H14-Ca (H-800)

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

**This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.**

Valid Since  
May 9<sup>th</sup>, 2012  
Changchun, China

Representative:  
Yu Ge  
Dirui Industrial Co., Ltd.   
于歌  
(name and signature or equivalent marking of authorized person)

\_\_\_\_\_  
(place and date of issue)