



REPUBLICA MOLDOVA

# LICENȚĂ

**Seria A MMII**

**Nr. 044322**

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență

**Societatea cu Răspundere Limitată  
"BIOSISTEM MLD"**

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența

**\* Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale \***

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

**Semnătura conducătorului  
autorității de licențiere**

**Director al Camerei de Licențiere**

**Valentin GUZNAC**



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



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

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

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

Республика Молдова, MD-2068  
мун. Кишинэу, бул. 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  
in moneda nationala 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

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





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.  
Secția fonduri speciale și informații curente

**EXTRAS**  
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 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,**

Asociați:

- 1. POIATA VITALIE , IDNP 0983103892591**  
cota 1803.60 lei, ce constituie 33,4 %
- 2. NASEDCHIN ALEXANDR , IDNP 2002001070747**  
cota 1798.20 lei, ce constituie 33,3 %
- 3. KOJEVNIKOV DMITRII , IDNP 0972305012362**  
cota 1798.20 lei, ce constituie 33,3 %.

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: 11.07.2016.

Specialist principal  
tel. 022-266-252

  
**Lazari Aliona**



## **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>Alexandru Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

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

Nr.  
№ **A1950104**

din  
от **26.12.2019**

**1. Destinația / Назначение**

Pentru participarea la proceduri de achiziții publice

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

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

**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 până la / Действителен до 10.01.2020**

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

**Şef DDF Rîșcani**  
**a DGAF mun.Chișinău**

Funcția/Dолжность

L.Ş/ М.П.

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



**Ana STOICOV**

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 26.12.2019 ora 13:46:18  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,02)



Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;  
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;  
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

**Către Grupul de lucru pentru evaluarea  
licitației publice Nr. ocds-b3wdp1-MD-1575462748171  
din 09.01.2020 din cadrul IMSP AMT Riscani**

### **Declarație**

Prin prezenta, SRL „Biosistem-MLD”, declara ca, reagenții sunt în ambalajul producătorului.

27.12.2019

\_\_\_\_\_ Poiata Vitalie

**L.Ș.**



21.08.2016  
Izmir / Turkey

## DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

FOR ANNEX II LIST A which includes HIV, Hepatitis B and Hepatitis C tests; the Notified Body must verify that the product meets the Common Technical Specification (CTS) and must release each batch of product before it is placed on the European market. The batch release often requires testing. These have EC Design Examination certificates by the notified body.

FOR ANNEX III which includes all other tests for Professional use; the manufacturer prepares a declaration of conformity in a similar way to the general devices.

For the above mentioned reason, we hereby declare that we provide CE Certificate for only the Hepatitis B, Hepatitis C and HIV tests for Professional use. For the group of other Professional tests; it is enough to present a self-Declaration of Conformity to the EU standards.

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



## EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**HBsAg Test**

**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TURKLAB Tıbbi Mal. San. Tic. A.Ş.**  
**ITOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

**CE 1434**

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

Application No. 45/2016  
Contract No. MD-18/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-57/2016**

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**HBsAg Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 45/2016  
Contract No. MD-18/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-52/2016**

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**Anti-HCV Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 43/2016  
Contract No. MD-16/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-53/2016**

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti-HCV Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 43/2016  
Contract No. MD-16/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-54/2016**

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device, List A:

**Anti-HBs Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 44/2016  
Contract No. MD-17/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-55/2016**

Full Quality Assurance System

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No:15 Tekeli Menderes**  
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti-HBs Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 44/2016  
Contract No. MD-17/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-58/2016**

EC Design-Examination

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device, List A:

**Anti - HIV 1/2 Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**  
manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 46/2016  
Contract No. MD-19/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-59/2016**

Full Quality Assurance System

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti - HIV 1/2 Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

**CE 1434** PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

Application No. 46/2016  
Contract No. MD-19/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-51/2016**

EC Design-Examination

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device for self-testing:

**hCG Pregnancy Test  
Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Rapidan  
Tester®, Rapidan Compact®, Labmen®**  
manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

was examined by PCBC according to Annex III p. 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

**CE 1434** PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

Application No. 42/2016  
Contract No. MD-15/2016

Module A1



# CERTIFICATE

No. J - 2670/2/2018

This is to certify that:

**TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.**  
**Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5**  
**35621 Çiğli, İzmir, Turkey**  
**Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey**

is in conformance with

**EN ISO 9001:2015**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro diagnostic medical devices  
intended for self-testing and professional use,  
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019  
QMS



  
**Anna Wyroba, M.Sc.**  
Vice President



Certificate No. **J-2670/2/2018**  
Issued under the Contract No. 2897/JM/3/2017  
Date of certification decision: 24.08.2018  
Bears the PCBC hologram.  
Warsaw, 24.08.2018



# CERTIFICATE

No. M - 56/2/2018

This is to certify that:

**TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.**  
**Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5**  
**35621 Çiğli, İzmir, Turkey**  
**Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey**

is in conformance with

**EN ISO 13485:2016**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro diagnostic medical devices  
intended for self-testing and professional use,  
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019  
QMS



*Anna Wyroba*  
**Anna Wyroba, M.Sc.**  
Vice President





Certificate No. **M - 56/2/2018**

Issued under the Contract No. 2897/JM/3/2017

Date of certification decision: 24.08.2018

Bears the PCBC hologram.

Warsaw, 24.08.2018

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

06.12.2019

**To: Whoever it may concern**

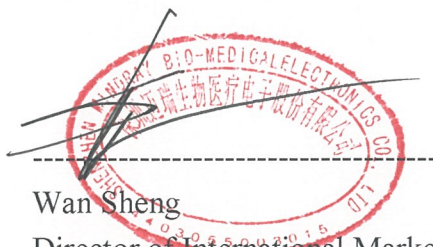
**MANUFACTURER'S AUTHORIZATION**

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** ("Mindray") manufacturer of Hematology analyzer **BC-5150**, hereby authorize: **Biosistem-mld SRL** with business office at Albisoara 16/1 ap.7 , Chisinau, Republic of Moldova, as the **exclusive one company** to submit a bid, and subsequently negotiate and sign the Contract for procurement of reagents for medical equipment according to **Tender ocds-b3wdp1-MD-1575462748171 dd. 09.01.2020 organized by IMSP Asociația Medicală Teritorială Botanica** for the year 2020 for the above mentioned products in **Moldova**.

This authorization is valid from the date of issuance up to conclusion of the tender project. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any further compensation to you.

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

Best Regards,



Wan Sheng

Director of International Marketing Department, In-Vitro Diagnostic Division  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

06.12.2019

**To: Whoever it may concern****MANUFACTURERS DECLARATION**

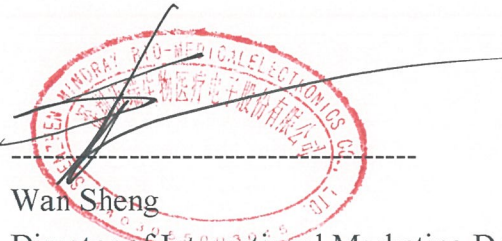
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("**Mindray**") manufacturer of Hematology analyzer **BC-5150**, do hereby declare that:

The following reagents:

- 105-004045-00 M-52D Diluent
- 105-003724-00 M-52DIFF Lyse
- 105-004307-00 M-52LH Lyse
- 105-002225-00 Probe Cleanser
- 105-000134-00 Control 3 x 3.5ml Tri-pack (1L, 1N, 1H)

are manufactured by our company exclusively for the use with the closed-system BC-5150 Hematology Analyzers. The usage of reagents is also described in the user manual of the analyzer at the point: "*2.7. Reagents, Controls and Calibrators*", page 2-12.

Best Regards,



Wan Sheng

Director of International Marketing Department, In-Vitro Diagnostic Division  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

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

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

# Declaration of Conformity



**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-5000

Including reagents as following:

**M-52D DILUENT**

**M-52DIFF LYSE**

**M-52LH LYSE**

**PROBE CLEANSER**

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

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

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

**Standards Applied:**

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

**Start of CE-Marking:** 2013-9-26

**Place, Date of Issue:** Shenzhen, 2013-9-26

**Signature:** \_\_\_\_\_

**Name of Authorized Signatory:** Mr.tan ChuanBin

**Position Held in Company:** Manager ,Technical Regulation

# Declaration of Conformity



**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-5150

Including reagents as following:

**M-52D DILUENT**

**M-52DIFF LYSE**

**M-52LH LYSE**

**PROBE CLEANSER**

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

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

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

**Standards Applied:**

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

**Start of CE-Marking:** 2013-9-26

**Place, Date of Issue:** Shenzhen, 2013-9-26

**Signature:** \_\_\_\_\_

**Name of Authorized Signatory:** Mr.tan ChuanBin

**Position Held in Company:** Manager ,Technical Regulation

## Applied Standards List

**Product:** Auto Hematology Analyzer

**BC-5150、BC-5000**

Including reagents as following:

**M-52D DILUENT**

**M-52DIFF LYSE**

**M-52LH LYSE**

**PROBE CLEANSER**

### Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2009	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer( labeling ) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

## Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

AMZ MEDICAL



America

# CERTIFICATE

No. QS5 17 07 44751 097

## 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:

Design and Development, Production and Distribution of Medical Electronic 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, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

## 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.:

M2606

Effective Date:

2017-07-01

Expiry Date:

2020-06-30

Earl Buckmiller

Director, Quality Systems & MS Cert. Body



Page 1 of 3

TÜV SÜD America Inc.  
10 Centennial Drive  
Peabody, MA 01960  
USA

TÜV®







America

# CERTIFICATE

No. QS5 17 07 44751 097

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

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
**Bldg 9-13, Baiwangxin High-Tech Industrial Park**  
**Baimang, Xili Town**  
**Nanshan, 518108 Shenzhen**  
**PEOPLE'S REPUBLIC OF CHINA**

Design and Development, Manufacturing of 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, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

**Effective Date:** 2017-07-01  
**Expiry Date:** 2020-06-30

Earl Buckmiller  
 Director, Quality Systems & MS Cert. Body

Page 2 of 3

TÜV SÜD America Inc.  
 10 Centennial Drive  
 Peabody, MA 01960  
 USA

TÜV®





America

# CERTIFICATE

No. QS5 17 07 44751 097

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
**1203 Nanhuan Avenue**  
**Guangming District**  
**518016 Shenzhen**  
**PEOPLE'S REPUBLIC OF CHINA**

Design and Development, Production and Distribution of Medical Electronic 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, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories (Ultrasonic Transducer), Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

**Effective Date:** 2017-07-01  
**Expiry Date:** 2020-06-30

Earl Buckmiller  
 Director, Quality Systems & MS Cert. Body

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TÜV SÜD America Inc.  
 10 Centennial Drive  
 Peabody, MA 01960  
 USA

TÜV®





Product Service

# CERTIFICATE

No. Q5 17 03 44751 089

**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 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). See also notes overleaf.

**Report No.:** SH1705528

**Valid from:** 2017-09-01

**Valid until:** 2020-08-31

**Date,** 2017-06-28

Stefan Preiß



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Product Service

**CERTIFICATE****No. Q5 17 03 44751 089****Applied Standard(s):**

EN ISO 13485:2016  
 Medical devices - Quality management systems -  
 Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

**Facility(ies):**

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

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Bldg 9-13, Baiwangxin High-Tech Industrial Park,  
 Baimang, Xili Town, Nanshan, 518108 Shenzhen,  
 PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Biomedical Electronics Co., Ltd.  
 1203 Nanhuan Avenue, Guangming District, 518106  
 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**



Product Service

**Attachment for Certificate No. Q5 17 03 44751 089**

**Dated: 2017-06-28**

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, Wearable ECG Recorder,

Anesthesia Machine and Accessories, Ventilator,

Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,

Ultrasonic Diagnostic Equipment and Accessories,

Digital Radiography System, Radiography System, Magnetic Resonance Imaging System

Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay 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 Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer,

Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Munich, CRT, 2017-06-28

Stefan Preiß

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