

-----:
ORDIN DE PLATA NR.: 2432 TIP.DOC. 1 :
DATA EMITERII:joi, 23 noiembrie :
=====:
PLATITI: 3500-00 LEI: Trei Mii Cinci Sute lei 00 ban :
i :
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP SR CAH CONTUL DE PLATI/CODUL IBAN :
UL MD39VI0000000022514095MDL :
CODUL FISCAL :1009603003860 / :
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
B.C."VICTORIABANK"S.A. :VICBMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1698750268159 din 2: :
4.11.2023 : :
: :
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:23/11/2023 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONducator:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNMA0GCSqG:
SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
L.S. (semnatura electronica) :
CONducator: (semnatura manuala) :
CONTABIL-SEF: (semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
-----:
MOTIVUL REFUZULUI : L.S. :
-----:



GUVERNUL  
REPUBLICII  
MOLDOVA



SERVICIUL FISCAL DE STAT



# CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.  
N<sup>o</sup>

Din  
Ot

1

**DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ**

**Codul fiscal/Numărul de identificare**

Фискальный код/Идентификационный номер

**Denumirea**

Наименование

2

**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**

lei/лей

3

**VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО**



**Prezentul certificat este eliberat în temeiul Art. 131, alin. (5<sup>3</sup>) din Codul fiscal nr. 1163/1997, în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Antreprenorului/Сертификат выдан в соответствии со ст. 131, п. (5<sup>3</sup>) Налогового кодекса N<sup>o</sup>1163/1997, на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Предпринимателя**

Generat și semnat de Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) la

**Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /  
Сертификат подписан электронной подписью в соответствии с Законом N<sup>o</sup> 124 от 19.05.2022**

Certificatul este descărcat de pe Portalul Guvernamental al Antreprenorului (<https://mcabinet.gov.md>) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală.  
Verificarea autenticității semnăturii electronice poate fi realizată la adresa: <https://msign.gov.md>.

Сертификат выгружен с Правительственного Портала Предпринимателя (<https://mcabinet.gov.md>) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы, выдаваемые на бумаге органами налоговой администрации.  
Проверку подлинности электронной подписи можно осуществить по адресу: <https://msign.gov.md>.



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

Republica Moldova, MD-2068  
mun. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDM2X329

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

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московей, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDM2X329

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

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

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





## 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**

## **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>

Otorga la presente / Grants this

## ACREDITACIÓN 12/PPI020

a

### BioSystems, S.A. (PREVECAL)

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

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



D. José Manuel Prieto Barrio  
Presidente

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

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

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

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

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

6M91021910

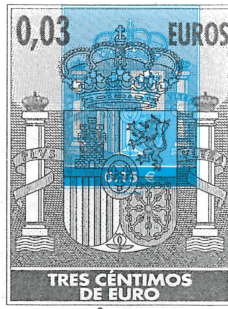
06/2019



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



CLASE 8ª



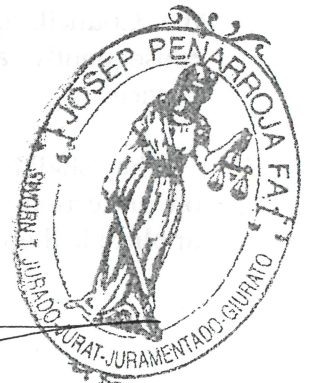
*Traducción Jurada* *Official translation*

*Josep Peñarroja Fa*  
*Intèrprete Jurado de Inglés*  
*Official Translator of English*

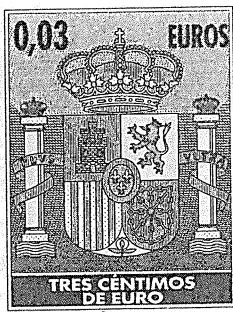
*Certifica que la que antecede es traducción*  
*fiel y completa al inglés de un documento*  
*redactado en español.*

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

*Barcelona,* - 3 MAR 2020







0N9696073

CLASE 8.<sup>a</sup>

## Traducción Jurada

[Coat of arms  
of Spain]**MINISTRY  
OF HEALTH**[Logo]  
Spanish Medicines and  
Medical Devices Agency

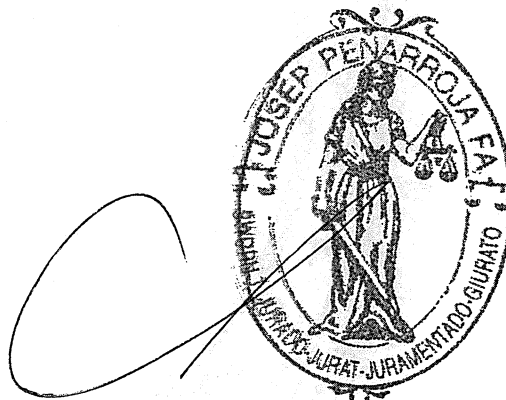
### NOTIFICATION

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

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

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

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



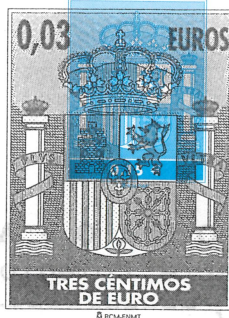
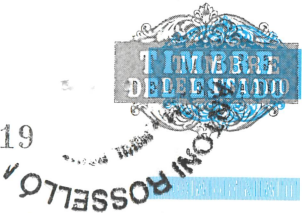
You are hereby advised that:

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

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

0N98961929

06/2019



CLASE 8.<sup>a</sup>

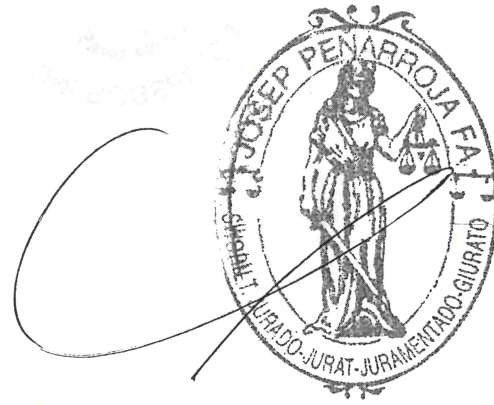
# Traducción Jurada

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

E-MAIL:  
mpizarro@aemps.es

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

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



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

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

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

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



*Antonio Roselló Mestre*



# CERTIFICATO DI ACCREDITAMENTO

## Accreditation Certificate

ACCREDITAMENTO N.  
ACCREDITATION N.

**0017P REV. 02**

EMESSO DA  
ISSUED BY

**DIPARTIMENTO LABORATORI DI PROVA**

SI DICHIARA CHE  
WE DECLARE THAT

**BIO-GROUP MEDICAL SYSTEM S.r.l.**

Sede/Headquarters:

- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI  
DELLA NORMA

**UNI CEI EN ISO/IEC 17043:2010**

MEETS THE REQUIREMENTS  
OF THE STANDARD

**ISO/IEC 17043:2010**

QUALE

**Organizzatori di prove valutative interlaboratorio**

AS

**Proficiency Testing Provider**

Data di 1<sup>a</sup> emissione  
*1st issue date*  
**14-11-2018**

Data di revisione  
*Review date*  
**18-10-2022**

Data di scadenza  
*Expiring date*  
**12-11-2026**

L'accreditamento attesta la competenza, l'imparzialità e il costante e coerente funzionamento dell'Organizzazione relativamente al campo di accreditamento riportato nell'Elenco Schemi allegato al presente certificato di accreditamento.

Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi e può essere sospeso o revocato o ridotto in qualsiasi momento nel caso di inadempienza accertata da parte di ACCREDIA.

La validità dell'accreditamento può essere verificata sul sito web ([www.accredia.it](http://www.accredia.it)) o richiesta al Dipartimento di competenza.

*The accreditation attests competence, impartiality and consistent operation in performing laboratory activities, limited to the scope detailed in the attached Enclosure.*

*The present certificate is valid only if associated to the annexed Lists and can be suspended, withdrawn or reduced at any time in the event of non fulfilment as ascertained by ACCREDIA.*

*Confirmation of the validity of accreditation can be verified on the website ([www.accredia.it](http://www.accredia.it)) or by contacting the relevant Department.*

Il QRcode consente di accedere direttamente al sito [www.accredia.it](http://www.accredia.it) per verificare la validità del certificato di accreditamento rilasciato al CAB.

La data di revisione riportata sul certificato corrisponde alla data di aggiornamento / di delibera del pertinente Comitato Settoriale di Accreditamento. L'atto di delibera, firmato dal Presidente di ACCREDIA, è scaricabile dal sito [www.accredia.it](http://www.accredia.it), sezione 'Documenti'

*The QRcode links directly to the website [www.accredia.it](http://www.accredia.it) to check the validity of the accreditation certificate issued to the CAB.*

*The revision date shown on the certificate refers to the update / resolution date of the Sector Accreditation Committee. The Resolution, signed by the President of ACCREDIA, can be downloaded from the website [www.accredia.it](http://www.accredia.it), 'Documents' section.*

ACCREDIA è l'Ente Unico nazionale di accreditamento designato dal governo italiano, in applicazione del Regolamento Europeo 765/2008.

*ACCREDIA is the sole national Accreditation Body, appointed by the Italian government in compliance with the application of REGULATION (EC) No 765/2008.*



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

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47863 Italy  
Ensure and declare with sole responsibility that the products:

Internal code: MSEQSCH12 EDMA Code: 38220000	Commercial name: QS Clinical Chemistry 12 First lot introduced in market: 101-AA
Internal code: MSEQSHE12 EDMA Code: 38220000	Commercial name: QS Hematology 12 First lot introduced in market: 202-AA
Internal code: MSEQSCO12 EDMA Code: 38220000	Commercial name: QS Coagulation 12 First lot introduced in market: 303-CC
Internal code: MSEQSIM12 EDMA Code: 38220000	Commercial name: QS Immunology 12 First lot introduced in market: 102-CC
Internal Code: MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBA1C 12 First lot introduced in market: 161-CA

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us. To this purpose, we guarantee and declare, on our own responsibility, what follows:

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

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

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

Talamello, 25/08/2021

The Executive Manager  
Paolo Buonvicino

**BIO-GROUP**  
**MEDICAL SYSTEM Srl**

Con socio unico  
Loc. Campiano 9/B – 47867 Talamello (RN)  
Rid. C.Fisc. 00964170419



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

### Declaration of conformity certificate

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

Internal code: MSEQUALITYCH EDMA Code: 38220000	Commercial name: QS Clinical Chemistry First lot introduced in market: 112-NB
Internal code: MSEQUALITYPS EDMA Code: 38220000	Commercial name: QS Specific Protein First lot introduced in market: 220-NB
Internal code: MSEQUALITYEF EDMA Code: 38220000	Commercial name: QS Electrophoresis First lot introduced in market: 220-NB
Internal code: MSEQUALITYE8 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI EDMA Code: 38220000	Commercial name: QS Immunology First lot introduced in market: 360
Internal code: MSEQUALITYB EDMA Code: 38220000	Commercial name: QS Bacteriology First lot introduced in market: 326
Internal code: MSEQUALITYS EDMA Code: 38220000	Commercial name: QS Serology First lot introduced in market: 1020-SI
Internal code: MSEQUALITYU EDMA Code: 38220000	Commercial name: QS Urine First lot introduced in market: 002-U
Internal Code: MSEQUALITYH EDMA Code: 38220000	Commercial name: QS HBA1C First lot introduced in market: 001-H
Internal Code: MSEQUALITYD EDMA Code: 38220000	Commercial name: QS Drug of Abuse First lot introduced in market: 330-D
Internal Code: MSEQUALITYSO EDMA Code: 38220000	Commercial name: QS FOB First lot introduced in market: 110-F
Internal Code: MSEQUALITYESR EDMA Code: 30021095	Commercial name: QS ESR First lot introduced in market: 001-V
Internal Code: MSEQUALITYCM EDMA Code: 38220000	Commercial Name: QS Cardiac Marker First lot introduced in market: 201-C

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

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

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



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

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

Talamello, 25/08/2021

The Executive  
Manager  
Paolo Buonvicino

Declaration of Conformity V 1.0

# 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



Declaration of Conformity V 1.0

## 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 (labelling ) 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