

```

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ORDIN DE PLATA NR.: 2496                                TIP.DOC. 1 :
                                DATA EMITERII:miercuri, 13 decem:
=====:
PLATITI: 25000-00          LEI: Douazeci si Cinci Mii lei 00 b :
ani                                                                :
:                                                                    :
=====:
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 CFM Ba    CONTUL DE PLATI/CODUL IBAN      :
lti                          MD63ML000000002251921512          :
                                CODUL FISCAL :1003602150710 /    :
:                                                                    :
=====:
PRESTATORUL BENEFICIAR          CODUL BANCII:
BC"Moldindconbank"S.A.          :MOLDMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1700852027766 din 1: :
4.12.2023 : :
: :
: : L.S. :
=====:
                                _____:
                                CODUL TRANZACTIEI:001: _____:
                                DATA PRIMIRII:13/12/2023 : SEMNATURILE :
                                DATA EXECUTARII: : EMITENTULUI :
                                :-----:
CONducATOR:Web Poiata Vitalie
MIIGYwYJKoZIhvcNAQcCoIIGVDCcBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSqG:
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YDVQqIEwdNb2xkb3ZhmREwDwYDVQqHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
: (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCcBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLUL1vbGRpbmRjb25iYW5rMB4X:
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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDM2X329.

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*

*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>

## Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, *Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale* nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/01	<b>BIOSYSTEMS S.A.</b> Costa Brava 30 08030 Barcelona Spain	Design, development, manufacture, distribution, installation and service of instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics.
/02	<b>BIOSYSTEMS, S.A.</b> Pol. Ind. Can Tapiolas Naves 12, 13, 21 y 22 08110 Montcada i Reixac (Barcelona) Spain	Reagent labelling and assembly. Storage of raw materials for instruments, instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. Dispatched of stored product.

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**  
Costa Brava 30  
08030 Barcelona  
Spain

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.  
Storage of raw materials for instruments, instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched or stored product.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-12-19 until 2025-12-18.  
First certification 1996

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

Scope: Design and development, production, distribution and servicing  
of instruments and reagents for clinical diagnostic.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92648791-40  
Effective date: 2022-12-12  
Expiry date: 2025-12-12  
Issue date: 2022-12-12

*J. Pyclik*



Jaroslav Pyclik  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010, Montcada i Reixac – Barcelona, Spain	Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic.

Report No.: 92648791-40  
Effective date: 2022-12-12  
Expiry date: 2025-12-12  
Issue date: 2022-12-12



*J. Pyclik*



TÜV Rheinland LGA Products GmbH  
Zertifizierungsstelle

Jaroslav Pyclik  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

## ***CERTIFICAT DE AUTORIZARE***

Prin prezentul este autorizata

SRL Biosistem-MLD  
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica  
Moldova produsele

BIOSYSTEMS SA  
cu sediul C/Costa Brava 30  
08030 Barcelona (Spain)



Xavier Palomar  
Area Manager  
27-April-2013



**Biosistem-mld SRL**

Albisoara 16/1 ap.7

Chisinau, Moldova

tel.+ 373 22 808-719 / 808 - 517

fax.+ 373 22 808-519

2<sup>nd</sup> April 2021

**LETTER OF AUTHORIZATION**

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, manufacturer of BC-20s, BC-30s, BC-5000, BC-5150, BC-5300, BC-5310 CRP, BC-5380, BC-5390 CRP, BC-6000, BC-6200, BC-6800, BC-6800 Plus, BS-230, BS-240Pro, BS-430, BS-800, BS-2000M with relevant reagents and consumables ("**Product(s)**"), hereby certify that we authorize **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Moldova ("**You**") as our distributor to import, distribute, register, and do the Sanitary Registration of the Products in **Moldova** ("**Territory**").

This Letter of Authorization is valid from the date of issuance to **December 31, 2023**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to **You**.

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

Best regards,



Duan Liang

Sales Manager of Sales and Marketing Division, CIS  
**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



**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

**To: Whoever it may concern**

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

**04.12.2019**

### **LETTER OF AUTHORIZATION**

We, **BIO GROUP MEDICAL SYSTEM Srl** located in Loc. Campiano 9B Talamello (RN) Italy VAT IT00964170419, do hereby authorize:

**Biosistem-mld SRL** with business office at Albisoara 16/1 ap.7 , Chisinau, Republic of Moldova

to be our official representative to submit bids, and subsequently negotiate and sign contracts for procurement of External quality controls for hematology in Republic of Moldova.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

*The Executive Manager*  
*Adelmo Ciccioni*

**BIO GROUP  
MEDICAL SYSTEM SRL**  
Loc. Campiano 9/B – 47867 Talamello (RN)  
P.Iva / C.Fisc.: 00964170419

Otorga la presente / Grants this

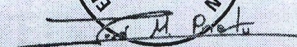
## ACREDITACIÓN 12/PPI020

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

# CERTIFICATO DI ACCREDITAMENTO

## Accreditation Certificate

ACCREDITAMENTO N. **0017P REV. 00**  
ACCREDITATION N.

EMESSO DA **DIPARTIMENTO LABORATORI DI PROVA**  
ISSUED BY

SI DICHIARA CHE **BIO-GROUP MEDICAL SYSTEM S.r.l.**  
WE DECLARE THAT  
Sede/Headquarters:  
- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI **UNI CEI EN ISO/IEC 17043:2010**  
DELLA NORMA

MEETS THE REQUIREMENTS **ISO/IEC 17043:2010**  
OF THE STANDARD

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 modifica  
Modification date  
**14-11-2018**

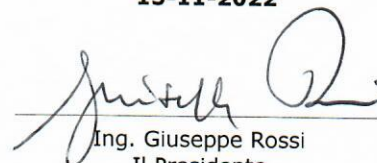
Data di scadenza  
Expiring date  
**13-11-2022**



Dott.ssa Silvia Tramontin  
Il Direttore di Dipartimento  
The Department Director



Dott. Filippo Trifiletti  
Il Direttore Generale  
The General Director



Ing. Giuseppe Rossi  
Il Presidente  
The President

L'accreditamento attesta la competenza tecnica 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, che possono variare nel tempo.

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

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure. The present certificate is valid only if associated to the annexed schedule, that may vary in the time.

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





**BIO GROUP – MEDICAL SYSTEM Srl**  
**Strumentazione e Diagnostici**  
 Loc. Campiano, 9/B – 47867 Talamello (RN)  
 e.mail: info@biogroupmedicalsystem.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-MSEQSCH12-MSEQSCH4 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-MSEQSE12 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC-MSEQSC12-MSEQSC4 EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI-MSEQSI12-MSEQSI4 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-MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBAIC 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.

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, January the 29<sup>th</sup>, 2019

**BIO GROUP**  
**MEDICAL SYSTEM SRL**  
 Loc. Campiano 9/B – 47867 Talamello (RN)  
 P.IVA C.Fisc. 0096170419

Cap. Soc. € 75.300,00 i.v. – Reg. Trib. Pesaro 7163 C.C.I.A.A. 98204 – P.IVA C.Fisc. 0096170419



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## **DECLARATION OF CONFORMITY**

To whom it may concern,

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

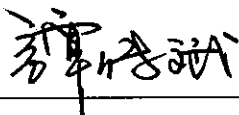
We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

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

**Products:** Attachment I

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

Place, Date Of Issue : Shenzhen, **2016-03-21**



**Signatory name:** Chuanbin Tan

signatory title: Technical Regulation Manager

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**ATTACHMENT I**

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

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		M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500 BC-5200	M-50D DILUENT M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300 BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator

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Auto Hematology Analyzer	BC-5380 BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800 BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300 BC-3300CT BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology

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		Calibrator
Auto Hematology Analyzer	BC-6600 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO( I ) LYSE M-53LEO( II ) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO( I ) LYSE M-53LEO( II ) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150 BC-5000	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator

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Urine Analyzer	UA-66、UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、BC-21s、 BC-30s、BC-31s	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent	/	/
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode

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		<p>Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit</p>
Chemistry Analyzer	BS-400、BS-420、 BS-480、BS-490	<p>ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit</p>
Chemistry Analyzer	Perfect plus	<p>ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit</p>



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

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		bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、 BS-180、BS-190	ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-230、BS-240	ISE Module, (No consumables) 4-channel Sodium Electrode Potassium Electrode

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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-430、BS-450	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, (No 4-channel consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml

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

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		System (RMS)
Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemiluminescence Immunoassay Analyzer	CL-2000i、CL-2200i	Hand-held bar code reader External vacuum pump External air pump Water supply module
Chemiluminescence Immunoassay Analyzer	CL-1000i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. Waste container
Chemiluminescence Immunoassay Analyzer	CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Hand-held bar code reader Reaction cuvettes. Waste container
$\alpha$ -Amylase ( $\alpha$ -AMY) Kit (IFCC Method)	/	/
Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/

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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(Turibidimetry 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)	/	/

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Creatine Kinase-MB Kit(IFCC Method)	/	/
HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N	/	/
Multi Control Sera P		
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N	/	/
Lipids Control P		
CK-MB Control N	/	/
CK-MB Control P		
Specific Proteins Control N	/	/
Specific Proteins Control P		
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/



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Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/
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	/	/
Multimmun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
$\alpha$ -L-Fucosidase Kit (CNPF method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/

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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	/	/
CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
aso Calibrator	/	/
Free Triiodothyronine (CLIA)	/	/
Free Thyroxine (CLIA)	/	/
Total Triiodothyronine (CLIA)	/	/
Total Thyroxine (CLIA)	/	/
Thyroid-stimulating Hormone (CLIA)	/	/
Follicle Stimulating Hormone (CLIA)	/	/
Luteinizing Hormone (CLIA)	/	/
Prolactin (CLIA)	/	/
Estradiol (CLIA)	/	/
Estriol (CLIA)	/	/
Testosterone (CLIA)	/	/
Progesterone (CLIA)	/	/
Total $\beta$ Human Chorionic Gonadotropin (CLIA)	/	/

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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 HCG Calibrators	/	/
Thyroid Function Multi Control	/	/
Reproductive Hormone 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 Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" Kit (ASO II) (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF Triple Control	/	/
Cystatin C Kit (CysC II) (Latex Immunoturbidimetric Method)	/	/

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Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein Kit (Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor Kit (RF II) (Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
$\beta$ 2-Microglobulin Kit ( $\beta$ 2-MG II) (Latex Immunoturbidimetric Method)	/	/
$\beta$ 2-Microglobulin Control	/	/
$\beta$ 2-Microglobulin Calibrator (for Serum)	/	/
$\beta$ 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/
Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
$\beta$ -Hydroxybutyrate ( $\beta$ -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)		
HbA1c control N		
HbA1c control P		
Rheumatism Control N		
Rheumatism Control P		
HCY Control N		
HCY Control P		
FUN Control P		
$\beta$ -2-MG Control		
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/

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Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

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	/	/
Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotrophic hormone(CLIA)	/	/
ACTH Calibrators	/	/

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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	/	/
Sample Diluent		

6M91021910

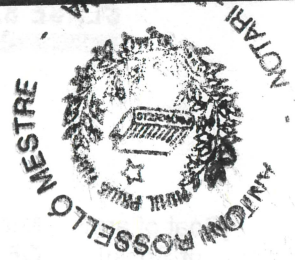
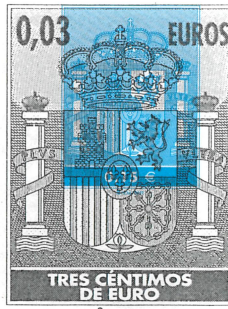
06/2019



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



CLASE 8ª



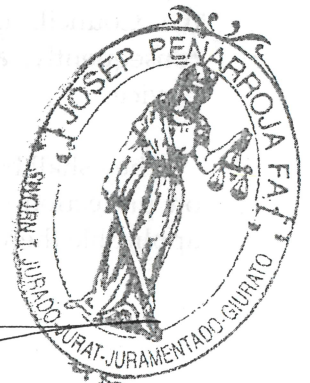
*Traducción Jurada* *Official translation*

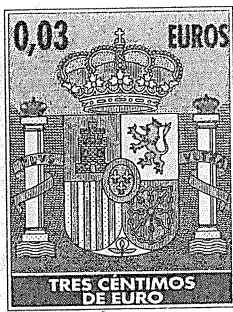
*Josep Peñarroja Fa*  
*Intérprete Jurado de Inglés*  
*Official Translator of English*

*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

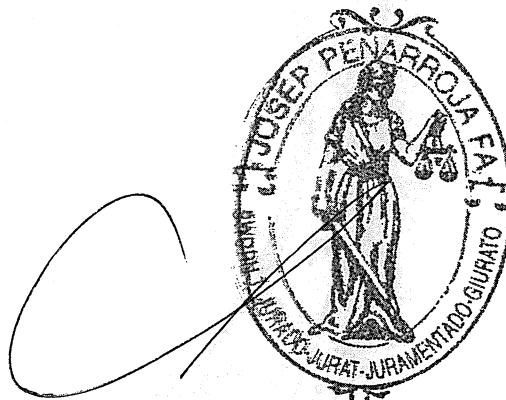
## NOTIFICATION

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:

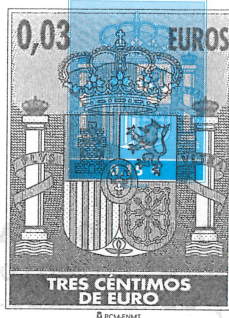
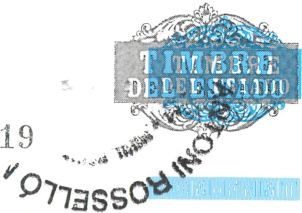
These products **do not** fall within the scope of Royal Decree 1662/2000, of 29 September, which transposes Directive 98/79/EC of the European Parliament and of the Council, of 27 October 1998, on in vitro diagnosis medical devices, and, consequently, are outside the sphere of competence of this Department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

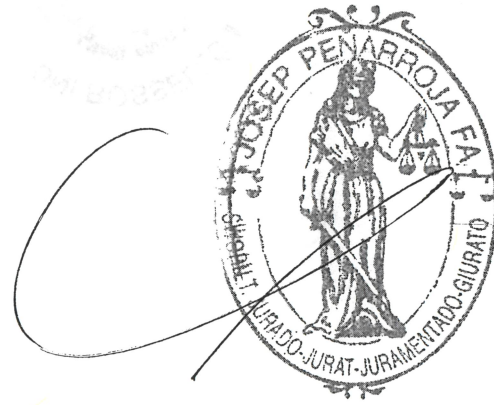
# Traducción Jurada

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]



**TESTIMONIO.- 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 Registrazione

Questo certificato è stato rilasciato a

**Microtrace Diagnostics srl**

Via Ca' di Vico 16, 47863 Novafeltria (RN) (Legal Site), Via IV Novembre 84,  
47863 Novafeltria (RN) (Operative site), Italy

come riconoscimento del Sistema Gestione Qualità aziendale in conformità alle Norme

**ISO 13485:2016**

Le attività coperte da questo certificato sono

**Progettazione e produzione di kit diagnostici in vitro per test di  
intolleranze alimentari e altri kit IVD**

Numero Del Certificato:

58429/C/0001/UK/It

Data d'emissione (originale):

13 Febbraio 2019

Data d'emissione:

13 Febbraio 2019

Emissione No:

1

Data di Scadenza:

12 Febbraio 2022

Emesso da:

*A nome del Scheme Manager*



If there is any doubt as to the authenticity of this certificate, please do not hesitate to contact the Head Office of the Group on [info@urs-certification.com](mailto:info@urs-certification.com).  
URS is a member of United Registrar of Systems (Holdings) Ltd, United House, 4 Hinton Road, Bournemouth, BH1 2EE, UK. Company Registration no. 5298466













# Certificate

No. Q5 044751 0164 Rev. 02

**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.  
 1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,  
 PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE

# Certificate

No. Q5 044751 0164 Rev. 02

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

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