ORDIN DE PLATA NR.: 2432 TIP.DOC. 1

DATA EMITERII:joi, 23 noiembrie

PLATITI: 3500-00 LEI: Trei Mii Cinci Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. suc."Invest" Chisinau
CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) IMSP SR CAHUL
CONTUL DE PLATI/CODUL IBAN
MD39VI000000022514095MDL
CODUL FISCAL :1009603003860 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.
CODUL BANCII:
:VICBMD2X

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1698750268159 din 24.11.2023

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:23/11/2023

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

L.S.

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORULUI L.S.

L.S.

Digitally Signed by Poiata Vitalie
Date: 2023.11.23 15:10:32 EET
Reason: MoldSign Signature
Location: Moldova

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI ANTREPRENORULUI

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. №: 1159048

Din От: 16.11.2023

1 DATE DESPRE CONTRIBUABIL/ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal/Numărul de identificare
Фискальный код/Идентификационный номер

1010600028048

Denumirea
Наименование

BIOSISTEM MLD S.R.L.

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

0,00 **lei**/лей

3 VALABIL PÂNĂ LA/ДЕЙСТВИТЕЛЕН ДО

01.12.2023

Prezentul certificat este eliberat în temeiul Art. 131, alin. (5^3) 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. (5^3) Налогового кодекса №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 16.11.2023 11:59:50

Prezentul certificat este semnat electronic în conformitate cu Legea nr. 124 din 19.05.2022 /
Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022

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. Московей, 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 MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

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

Asociaţii:
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 şi a întreprinzătorilor individuali şi 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

Date cu caracter personal

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

Acreditación

ENAC

Entidad Nacional de Acreditación

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

ENTIDAD NACIONAL DE ACREDITACIÓN ENAC

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.

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.

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)
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)

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

Código Validación Electrónica: L3Hf36Oo8A9IJ3Phr4
La vigencia de la acreditación y del presente certificado puede confirmarse en https://www.enac.es/web/enac/validacion-electronica o haciendo clic **aquí**

TIMBRE DEL ESTADO

0M7122959

06/2019

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

CLASE 8.ª

0,03 EUROS
TRES CÉNTIMOS DE EURO

ANTONI ROSSELLO MESTRE NOTARI

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

TRADUCTOR JURADO - JURAT
Josep Peñarroja Fa
OFFICIAL TRANSLATOR

JOSEP PEÑARROJA FA
TRADUCTOR JURADO-JURAT-JURAMENTADO-GIURATO

TIMBRE DEL ESTADO

0,03 EUROS
TRES CÉNTIMOS DE EURO

0N9696073

NOTARI - BARCELONA - MESTRE

CLASE 8.ª

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*

J. JOSEP PENARROJA FAI
TRADUCTOR JURAT - JURAMENTADO - GIURATO

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.

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]

JOSEP PENARROJA FA
TRADUCTOR-JURADO-JURAT-JURAMENTADO-GIURATO

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 Nº 453/2020 de la Sección Segunda.----------

SELLO DE LEGITIMACIONES Y LEGALIZACIONES

COLEGIO NOTARIAL DE CATALUÑA

FE PÚBLICA NOTARIAL

CONSEJO GENERAL DEL NOTARIADO ESPAÑOL

NOTARIADO EUROPA

NIHIL PRIUS FIDE

ANTONI ROSSELLÓ MESTRE

47584805

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

QUALE / *AS* **Organizzatori di prove valutative interlaboratorio** / ***Proficiency Testing Provider***

Data di 1ª 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 vigenza dell'accreditamento può essere verificata sul sito web (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) or by contacting the relevant Department.

Il QRcode consente di accedere direttamente al sito 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, sezione 'Documenti'
The QRcode links directly to the website 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, '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.

ACCREDIA - Dipartimento Laboratori di prova

Sede operativa, legale e amministrativa: Via Guglielmo Saliceto, 7/9 | 00161 Roma - Italy
Tel. +39 06 8440991 | Fax +39 06 8841199
info@accredia.it | www.accredia.it | Partita IVA - Codice Fiscale 10566361001

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) 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)
P.IVA / C.Fisc. 00964170419

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 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.

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

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 CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-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
ENISO 18113-2:2009	I 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

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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