ORDIN DE PLATA NR.: 615 TIP.DOC. 1

DATA EMITERII:25 februarie 2021

PLATITI: 800-00 LEI: Opt Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD95ML0000000002251429243
CODUL FISCAL :1010600028048 /

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

BENEFICIAR (R) IMSP Spital ul Clinic Municipal Sfinta Treime
CONTUL DE PLATI/CODUL IBAN MD22ML0000000000225166614
CODUL FISCAL :1003600152592 /

PRESTATORUL BENEFICIAR BC"Moldindconbank"S.A.
CODUL BANCII: :MOLDMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la licitatia publica nr. 2103645: 1 din 27.02.2021

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:25/02/2021
DATA EXECUTARII:25/02/2021 16:54:0:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

L.S.

CONDUCATOR: _____
(semnatura manuala)

CONTABIL-SEF: _____
(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.02.25 17:17:38 EET
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

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 MD95ML0000000002251429243**.

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

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

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**
Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat și codul fiscal: **1010600028048.**
Data înregistrării de stat: **12.08.2010.**
Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Activitatea farmaceutică;
2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;
4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;
5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;
6 Consultații în domeniul sistemelor de calcul.
Capitalul social: **5400** lei.
Administrator: POIATA VITALIE, IDNP 0983103892591,
Asociați:
1. POIATA VITALIE , IDNP 0983103892591
cota 1803.60 lei, ce constituie 33,4 %
2. NASEDCHIN ALEXANDR , IDNP 2002001070747
cota 1798.20 lei, ce constituie 33,3 %
3. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

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.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2102242 **din** / от 16.02.2021

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil pînă la / Действителен до 03.03.2021

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

Șef DDF Rîșcani
a DGAF mun.Chișinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUȘ
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

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

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 16.02.2021 ora 14:09:46 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,44)

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131743 0001

Report No.: 10042449 010

Manufacturer:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Products:
In-vitro diagnostic Medical Devices for self-testing

(see attachment for products included)

Replaces Approval, Registration No.: HL 60088590 0001

Expiry Date: 2023-09-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2018-10-19

Date: 2018-10-19

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Allen Chen
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60131743 0001
Report No.: 10042449 010

Manufacturer:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Products:

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Triglyceride Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin/ Triglyceride Monitoring Systems
- Blood Pressure/Glucose/Cholesterol Monitoring Systems (assessment limited to Glucose/Cholesterol Monitoring)

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Allen Chen

Date: 2018-10-19

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture and distribution of Medical devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-10-19
Certificate Registration No.:	SX 60131746 0001
An audit was performed. Report No.:	50145079 001
This Certificate is valid until:	2021-09-17

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-10-19

Allen Chen

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60131746 0001
Report No.: 50145079 001

Organization:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Scope:

Products:

- In vitro diagnostic medical devices used in blood analytes and blood glucose monitoring including meter, test strips and control solutions for self-testing, near patient/point of care.
- Blood Pressure/Glucose/Cholesterol Monitoring System (assessment limited to Blood Pressure Monitoring)

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Allen Chen

Date: 2018-10-19

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

has established and applies a quality management system
for the following scope:

Design and Development, Manufacture and Distribution of in vitro diagnostic for self-testing (see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60089707 0001

An audit was performed. Report No.: 10042449 001

This Certificate is valid until: 17.09.2018

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 14.01.2014

K. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SY 60089707 0001
Report No.: 10042449 002

Organization:

Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Scope:

Products:

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Pressure/Glucose/ Cholesterol Monitoring Systems (Monitoring System is including meter, strip and control solution)

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2014-03-13

X. Ren

DECLARATION OF CONFORMITY

Manufacturer：
Bioptik Technology, Inc.
No.188, Jhonghua South Road, Gongguan Village,
Jhunan Township, Miaoli County, 35057 Taiwan

Authorized Representative：
MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Medical Device：

Product Group:
EasyTouch G Blood Glucose Monitoring System
- EasyTouch G Blood Glucose Test Meter (ET-101)
- EasyTouch Blood Glucose Test Strips (SG119)
- EasyTouch Glucose Control Solution (CG101)

EDMA Code:
21 06 01 Blood Glucose Meter
11 70 01 01 00 Glucose Test Strips
11 70 01 50 00 Calibrators and Controls

IVDD-Classification: 98/79/EC, Annex II, List B, Self-testing device

Standards Applied:

1. EN ISO 15197: 2015, In vitro diagnostic test systems-Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197: 2013).
2. EN ISO 14971: 2012, Medical devices-Application of risk management to medical devices.
3. EN ISO 13485: 2016/AC: 2016, Medical devices-Quality management systems - Requirements for regulatory purposes.
4. EN 60601-1-2: 2015, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral
5. EN 61010-1: 2010, Safety requirements for electrical equipment for measurement, control and laboratory use-part 1: General requirements.
6. EN 61010-2-101: 2017, Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment.
7. EN 61326-1: 2013, Electrical equipment for measurement, control and laboratory use-EMC requirements. General requirements
8. EN 61326-2-6: 2013, Electrical equipment for measurement, control and laboratory use-EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
9. EN ISO 17511: 2003, In vitro diagnostic medical devices- Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials.

10. EN 13612: 2002/AC: 2002, Performance evaluation of in vitro diagnostic medical devices.
11. EN ISO 23640: 2015, In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
12. EN 13532: 2002, General requirements for in vitro diagnostic medical devices for self-testing.
13. EN 62304: 2006/AC: 2008, Medical device software-Software life cycle processes.
14. EN 62366-1: 2015, Medical device-Application of usability engineering to medical devices
15. EN ISO 18113-1: 2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1: 2009)
16. EN ISO 18113-2: 2011, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
17. EN ISO 18113-3: 2011, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
18. EN ISO 18113-4: 2011, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
19. EN ISO 18113-5: 2011, In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
20. EN ISO 15223-1:2016, Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex I of the 98/79/EC

This declaration of conformity is based on the IVDD 98/79/EC Annex IV and is supported by a TÜV Rheinland LGA Products GmbH Annex IV Certificate, with reference to articles 1 and 3 of the IVDD.

Certificate No.: HL 60149810 0001
Issue date: 2020-12-04
Expiry date: 2023-09-17

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Bioptik Technology, Inc.

Miaoli, Feb. 04, 2021
Place, Date of issue

Carlos Wu
Carlos Wu, C.E.O.
Bioptik Technology, Inc.