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

Digitally signed by Poiata Vitalie
Date: 2024.10.24 12:55:08 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

CERTIFICATE

EC No 1434-IVDD-435/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

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

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

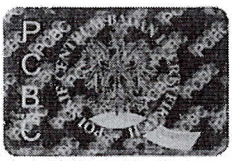
The date of the first issue of the Certificate: 29.08.2008

CE 1434

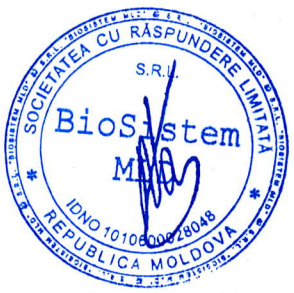
Application No: 56/2019
Module: H7

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem M IDNO 1010600020048 REPUBLICA MOLDOVA

Michał Pachowski, PhD
President



Certificate No 1434-IVDD-435/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019



CERTIFICATE

EC No 1434-IVDD-434/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

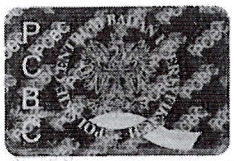
The date of the first issue of the Certificate: 29.08.2008

CE 1434

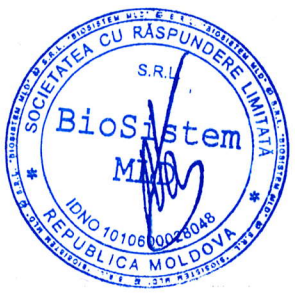
Application No: S6/2019
Module: H6

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSystem MD IDNO 1010600028048 REPUBLICA MOLDOVA

Michał Pachowski, PhD
President



Certificate No 1434-IVDD-434/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0056.2019/KW/MV/2023/0202

Warsaw, 13.04.2023

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli – Menderes Izmir, Turkey

To Whom it May Concern,

Polskie Centrum Badań i Certyfikacji S.A. informs about the update of EC Certificates No. 1434-IVDD-434/2019 and 1434-IVDD-435/2019 issued for TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş..

Current list of brands covered by the EC Certificates No. 1434-IVDD-434/2019 and 1434-IVDD-435/2019:

- Info®
- Toyo®
- Rapidan Tester®
- Test It

Implementation of the change does not represent a significant change in design or intended purpose under IVDR 2017/746 Article 110(3) and the related IVDD Certificates No. 1434-IVDD-434/2019 and 1434-IVDD-435/2019 issued 29.08.2019 remain valid until 28.08.2024.

Yours Sincerely,

Tomasz Koeber

Elektronicznie
podpisany przez
Tomasz Artur Koeber
Data: 2023.04.13
08:41:04 +02'00'

Head of Medical Device
Certification Division

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
BioSistem
IDNO 1010600028048
REPUBLICA MOLDOVA

EC DECLARATION OF CONFORMITY

In vitro Diagnostic Medical Devices in accordance with Directive 98/79/EC

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	HBsAg Test
Brand:	Rapidan® Tester, Toyo®, Info®, Test It®
Classification:	Annex II List A, 98/79/EC
Conformity Assessment Route:	Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Notified Body: Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw (Notified Body # 1434)

Start of CE Marking: 29.08.2008

Revision No: 9

Place, Date of Issue: Izmir, 18.07.2023

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB [illegible] MENDERES / İZMİR
FABRİKA: İTOB OSB [illegible] SK. NO:2 MENDERES / İZMİR
TEL: 0 232 [illegible] - FAX: 0 232 376 80 40
MENDERES V.D. 879 005 6209

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA

CE 1434

EC DECLARATION OF CONFORMITY

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Anti-HCV Test
Brand:	Rapidan® Tester, Toyo®, Info® , Test It®
Classification:	Annex II List A, 98/79/EC
Conformity Assessment Route:	Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Notified Body:	Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw (Notified Body # 1434)
Start of CE Marking:	29.08.2008
Revision No:	8
Place, Date of Issue:	Izmir, 08.02.2023
Signature	Kartal Yağlıdere General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. [illegible] MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. [illegible] SK. NO:2 MENDERES / İZMİR
TEL: 0 232 37[illegible] - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
BioSistem
IDNO 1010600028048
REPUBLICA MOLDOVA

CE 1434

CERTIFICATE

EC No 1434-IVDD-431/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

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

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

complies with requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

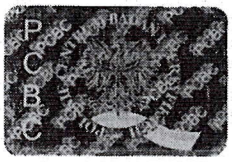
The date of the first issue of the Certificate: 29.08.2008

CE 1434

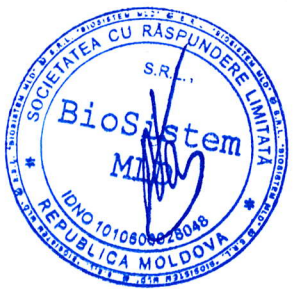
Application No: 58/2019
Module: H7

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. Biosistem IDNO 1010600028048 REPUBLICA MOLDOVA

Michał Pachowski, PhD
President



Certificate No 1434-IVDD-431/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019



CERTIFICATE

EC No 1434-IVDD-430/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

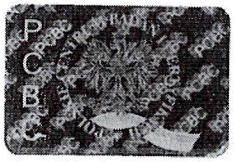
The date of the first issue of the Certificate: 29.08.2008

CE 1434

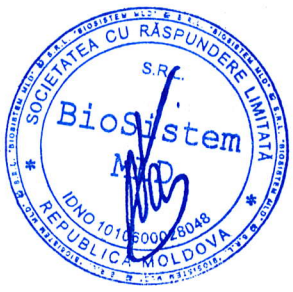
Application No: 58/2019
Module: H6

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem M IDNO 1010600028048 REPUBLICA MOLDOVA

Michał Pachowski, PhD
President



Certificate No 1434-IVDD-430/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0058.2019/KW/MV/2023/0204

Warsaw, 13.04.2023

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli – Menderes Izmir, Turkey

To Whom it May Concern,

Polskie Centrum Badań i Certyfikacji S.A. informs about the update of EC Certificates No. 1434-IVDD-430/2019 and 1434-IVDD-431/2019 issued for TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş..

Current list of brands covered by the EC Certificates No. 1434-IVDD-430/2019 and 1434-IVDD-431/2019:

- Info®
- Toyo®
- Rapidan Tester®
- Test It

Implementation of the change does not represent a significant change in design or intended purpose under IVDR 2017/746 Article 110(3) and the related IVDD Certificates No. 1434-IVDD-430/2019 and 1434-IVDD-431/2019 issued 29.08.2019 remain valid until 28.08.2024.

Yours Sincerely,

Tomasz Koeber

Elektronicznie
podpisany przez
Tomasz Artur Koeber
Data: 2023.04.13
08:41:41 +02'00'

Head of Medical Device
Certification Division

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BipSistem MLD IDNO 1010600028048 REPUBLICA MOLDOVA