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

Digitally signed by Poiata Vitalie
Date: 2024.11.29 14:43:20 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

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

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

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

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, bd. Moscovei, 14/1;

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld", va informeaza ca conform "***legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activităţii de întreprinzător***", cu modificarile ulterior adoptate de parlamentul RM, ***Importul, comercializarea, asistenţa tehnică si reparaţia 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.

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

_____Vitalie Poiata

L.Ş.

adresa: str. Albișoara 16/1 of.7, MD-2001 Chișinău, Republica Moldova
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

CE Declaration of Conformity CE

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Dirui Industrial Co., Ltd.
95 Yunhe Street New& High Tech. Development Zone
Changchun Jilin 130012 P.R. China

Authorized Representative : Emergo Europe
Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis
IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture (where applicable)

DIRUI 1 ITEMS (GLU) **DIRUI 1 ITEMS (KET)** **DIRUI 1 ITEMS (PRO)**
DIRUI 2 ITEMS (PRO,GLU) **DIRUI 2 ITEMS(KET,GLU)**
DIRUI 3 ITEMS(PRO,PH,GLU) **DIRUI 3 ITEMS (PRO, KET,GLU)**
DIRUI 4 ITEMS (PRO,PH.BLD,GLU) **DIRUI 4 ITEMS (PRO,PH,SG,GLU)**
DIRUI 5 ITEMS (PRO,PH, BLD,KET,GLU)
DIRUI 8 ITEMS **DIRUI H8**
DIRUI 9 ITEMS
DIRUI A10 **DIRUI H10** **DIRUI E10** **DIRUI M10** **DIRUI H10-800**
DIRUI H11 **DIRUI H11-MA** **DIRUI H11-800**
DIRUI H11-800MA **DIRUI H12-800MA**
DIRUI H13-Cr **DIRUI H14-Ca**
DIRUI H13-Cr (H-800) **DIRUI H14-Ca (H-800)**

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:
Yu Ge
Dirui Industrial Co., Ltd.
于歌

(place and date of issue)

(name and signature or equivalent marking of authorized person)

BioSystems
REAGENTS & INSTRUMENTS

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard
Adenosine Deaminase (ADA) Standard
Albumin (Microalbuminuria) Standard
Anti-Streptolysin O (ASO) Standard
Antithrombin III Standard
Apolipoprotein A-I Standard
Apolipoprotein B Standard
b2-Microglobulin Standard
Bilirubin Standard
Biochemistry Calibrator
Biochemistry Calibrator (Human)
Cholesterol HDL/LDL Calibrator
CRP/CRP-hs Standard
Ferritin Standard
Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Prealbumin Standard
Protein Calibrators
Protein (urine) Standard
Rheumatoid Factors (RF) Standard

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct
a-Amylase-Pancreatic
Adenosine Deaminase (ADA)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
Aspartate Aminotransferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total)
Calcium-Arsenazo
Cholesterol
Cholesterol HDL direct
Cholesterol LDL direct
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
g-Glutamyltransferase (g-GT)
Glucose
Iron Ferrozine
Lactate dehydrogenase (LDH)
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Triglycerides
Urea/BUN UV
Uric acid

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)
Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)
Anti-Centromere B Antibodies (CENP-B)
Anti-Citrullinated Protein Antibodies (ACPA)
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)
Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:
AUTOIMMUNITY – INSTRUMENTS:

iPRO

RAPID TESTS – LATEX AGGLUTINATION:

Anti-Streptolysin O (ASO) - Slide
C-Reactive Protein (CRP) - Slide
Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon
TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

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-3600**
Including reagents as following:
M-30D DILUENT
M-30CFL LYSE
M-30R RINSE
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: 2011-01-14
Place, Date of Issue: Shenzhen, 2011-01-14

Signature: .....
Name of Authorized Signatory: Mr. Yang Long
Position Held in Company: Management Representative

BioSystems
REAGENTS & INSTRUMENTS

Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARATIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.

BioSystems
Costa Brava, 30
08030 BCN

Xavier Palomar
Area Manager
27-April-2011

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com

mindray

December 29th, 2020

LETTER OF DECLARATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd., ("Mindray")** manufacturer of Hematology analyzer **BC-30s,** do hereby declare that:

The following reagents:

- A12-000047 M-30D DILUENT
- A12-000084 M-30CFL LYSE
- 105-000405-00 Probe Cleanser
- 105-003223-00 SC-CAL PLUS Calibrator 2×3.0ml
- 105-003227-00 BC-3D Control 3 x 3.0ml Tri-pack(1L, 1N, 1H)

Are manufactured by our company exclusively for the use with the closed-system BC-30s Hematology Analyzers.

Sincerely yours,

Yang Yong
General Manager of Sales and Marketing Division, CIS & TUR
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

CE

Declaration of Conformity

This is to state that Technical Documentation (CL001, rev. 2.0) for product(s)

Coagulometer

(Model:CA-01, CA-02)

(IVD products other than those covered by Annex II, IVD for self-testing and devices for Performance evaluation according to manufacturer's declaration)

Manufactured by

CLINDIAG SYSTEMS CO., LTD

No.29 Zhiyuan Road, Jurong Economic Development Zone,

Zhenjiang, Jiangsu Province, China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EC for in Vitro Diagnostic Medical Device, Annex III (Excluding Section 6)

CLINDIAG SYSTEMS CO., LTD.

Authorized Signature(s)

Mr. Xu Xin

General Manager

Valid from May, 2018 to May, 2023

CE

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:	Pregnancy (hCG) Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 84 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Strep A Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Adenovirus Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 01 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Rotavirus Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 0209

CE

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:	Tuberculosis (TB) Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 61 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Rotavirus Adenovirus Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Malaria Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MAL. SAN. VE TİC. A.Ş. MERKEZ: İTOB O.S.B. 10017 SK. NO:15 MENDERES / İZMİR FABRİKA: İTOB O.S.B. 10017 SK. NO:2 MENDERES / İZMİR TEL: 0 232 376 80 81- FAX: 0 232 376 80 40 MENDERES V.D. 879 009 6209

CE

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:	Influenza A/B Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MALZ. SAN. VE TİC. A.Ş. MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40 MENDERES V.D. 879 009 6209

CE

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:	H.Pylori Ab Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002/AC:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:13 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 80 FAX: 0 232 376 80 40
MENDERES VD. 879 009 6209

CE

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:	H.Pylori Ag Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002/AC:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010600028046 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 80 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	SARS-CoV-2 IgM/IgG Ab Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 04.01.2021

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
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FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 80 FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Monkeypox Virus Ab Test
Brand:	Rapidan® Tester, Toyo®, Info®, TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
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MENDERES V.D. 879 009 0209

CE

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:	Strep A Test
Brand:	TEST IT®
Product Code:	TISA101
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Hemoglobin A1c (HbA1c) Test
Brand:	Rapidan® Tester, Toyo®, Info®, TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

Revision No: 0

Place, Date of Issue: Izmir, 28.02.2023

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
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MENDERES V.D. 879 009 6209

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
Biosistem
MLD
REPUBLICA MOLDOVA

CE

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:	Fecal Occult Blood (FOB) Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1008600028048 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Troponin I Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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-Syphilis Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
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MENDERES V.D. 879 009 6209

CE

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:	AYC.2.2 Agar
Brand:	TEST IT
Product Code:	TIAYC01
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 15223-1:2021 EN ISO 18113-1:2011 EN ISO 18113-2:2011
Revision No:	0
Place, Date of Issue:	Izmir, 28.04.2022
Signature	Kartal Yağlıdere General Manager

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

TÜRKLAB TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. ... İZMİR
FABRİKA: İTOB OSB MAH. ... İZMİR
TEL: 0 232 376 80 81 ... 376 80 40
MENDERES V.D. ...

CE

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:	AYC-SENSITIVE
Brand:	TEST IT
Product Code:	TIAYC02
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 15223-1:2021 EN ISO 18113-1:2011 EN ISO 18113-2:2011
Revision No:	0
Place, Date of Issue:	Izmir, 28.04.2022
Signature	Kartal Yağlıdere General Manager

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1017600028046 REPUBLICA MOLDOVA

TÜRKLAB TIBBİ MAL. SAN. VE TİC. A.Ş. MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR TEL: 0 232 376 80 81- FAX: 0 232 376 80 40 MENDERES V.D. 879 009 6209

CE

EC DECLARATION OF CONFORMITY

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

Manufacturer:	TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	One Step Multi-Drug Urine Test, 12A
Brand:	TEST IT®
Product References:	TIDOA1225A
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN 13975:2003
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 13612:2002/AC:2002
EN ISO 17511:2021
EN ISO 23640:2015
EN 13641:2002
EN ISO 15223-1:2021

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

Revision No/Revision Date: 0

Place, Date of Issue: Izmir, 29.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 60 61 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	COVID-19 Neutralizing Ab Test
Brand:	Rapidan® Tester, Toyo®, Info®, TEST IT
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1006600028048 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 20.05.2021

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
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FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Covid-19 Ag Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Revision No: 0

Place, Date of Issue: Izmir, 04.01.2021

Signature

Kartal Yağlıdere
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MENDERES V.D. 879 009 6209

CE

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:	COVID-19 TOTAL Ig ELISA
Brand:	Test-It®, Rapidan® Tester, Toyo®, Info®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1006600028048 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 02.07.2020

Signature

Kartal Yağlıdere
General Manager

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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	COVID-19 Real Time RT-PCR Kit
Brand:	Test-It®, Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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

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

Revision No: 0

Place, Date of Issue: Izmir, 02.03.2020

Signature

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General Manager

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MENDERES V.D. 879 009 6209

CE

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:	COVID-19 IgG ELISA
Brand:	Test-It®, Rapidan® Tester, Toyo®, Info®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1018600028048 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 02.07.2020

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
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FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 01 FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Dengue NS1 Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1007800028048 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

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General Manager

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FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR
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MENDERES V.D. 879 009 6209

CE

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:	Dengue NS1, IgG/IgM Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1010600040608 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

TÜRKLAB
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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

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:	Dengue IgG/IgM Test
Brand:	TEST IT®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

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 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1 REPUBLICA MOLDOVA

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature

Kartal Yağlıdere
General Manager

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TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
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CE

BIOSYSTEMS

BioSystems S.A., organizer of the training, CERTIFIES that

Mr. Nasedchin Alexandr

successfully participated in the service engineer's training
"Random Access Biochemistry Analyzer A15, A25"

May 18-22, Moscow 2009

Director of technical service department
Representative office "BioSystems S.A." Russia

Sergey Vasiliyev

"БИОСИСТЕМС, С.А."
Испания
"BIOSYSTEMS, S.A."

mindray

healthcare within reach

Cert.Code: YFPX2022081200003

CERTIFICATE

Award to

Vitalie

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Hematology

Classic 3-DIFF Series

Level: Service Professional

2022/06/28 - 2022/06/29

China

Cherry Yang
Manager
Training Department
Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date: 2022.08.12

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healthcare within reach

Cert.Code: YFPX2022082900006

CERTIFICATE

Award to

Nasedchin Alexander

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Hematology

Classic 3-DIFF Series

Level: Service Professional

2022/06/28 - 2022/06/29

China

Cherry Yang
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Training Department
Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date: 2022.08.29