

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*

L. Svirepova
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

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

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDM2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

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

Scrisoare de informare

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



Vitalie Poiata

L.Ș.



Declaration of Conformity



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 H11 | DIRUI H11-MA | DIRUI M10 |
| DIRUI H11-800MA | | DIRUI H10-800 |
| DIRUI H13-Cr | DIRUI H12-800MA | |
| DIRUI H13-Cr (H-800) | DIRUI H14-Ca | |
| | 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 Directive 98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:

Yu Ge

Dirui Industrial Co., Ltd. 睿瑞医疗科技

于歌 股份有限公司



(place and date of issue)

(name and signature or equivalent marking of authorized person)

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




Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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



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.

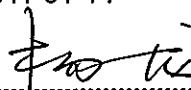
Standards Applied:

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

Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARAȚIA 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.



Xavier Palomar
Area Manager
27-April-2011



December 29th, 2020

LETTER OF DECLARATION

To whom it may concern,

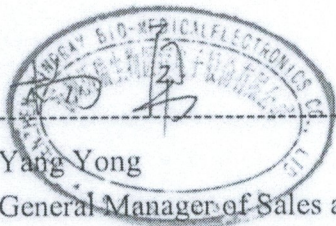
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("Mindray")
manufacturer of Hematology analyzer **BC-30s**, do hereby declare that:

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.



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

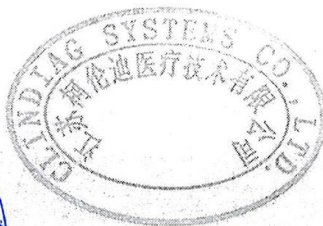
CLINDIAG SYSTEMS CO., LTD

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)

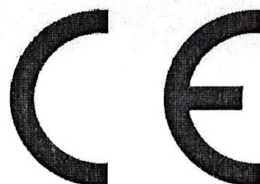


Valid from May, 2018 to May, 2023



Authorized Signatory

Mr. Xu Xin
General Manager



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

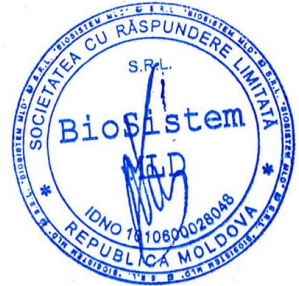
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

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 SOKAK NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SOK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 80 . FAX: 0 232 376 80 40
MENDERES Y.D. 879 609 6209



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

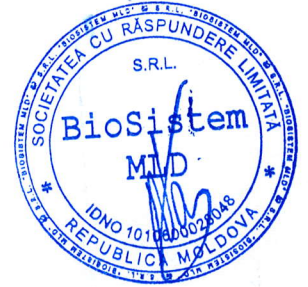
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



TÜRKLAB
TIBBİ MALZEME 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 87 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



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

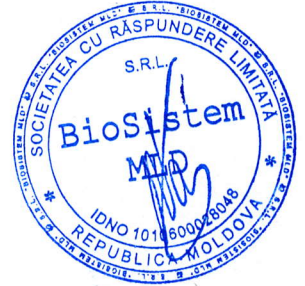
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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 Yağıldere
General Manager



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



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

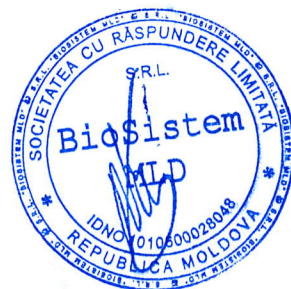
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

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. 979 009 6209



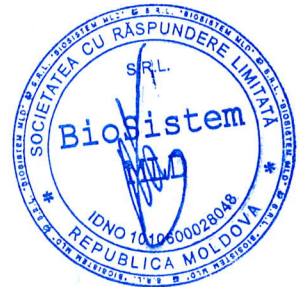
EC DECLARATION OF CONFORMITY

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

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - 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



Revision No: 0

Place, Date of Issue: İzmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SOK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10031 SOK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 40 - 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

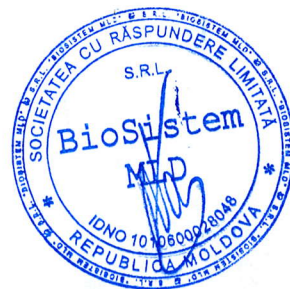
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



TURKLAB
TIBBİ MAL VE TIBBİ VE TİC. A.Ş.
MERKEZ: İTOB OSB MAM. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAM 10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 90 81- FAX: 0 232 376 90 40
MENDERES V.D. 879 009 6209



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

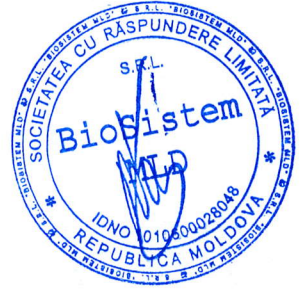
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağıldere
General Manager



TÜRKLAB
TIBBİ MAL. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSKAR MÜHÜRÜ SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSKAR MÜHÜRÜ 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: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: Influenza A/B Test
Brand: TEST IT®
Classification: Professional Use IVD, 98/79/EC
Conformity Assessment Route: Annex III

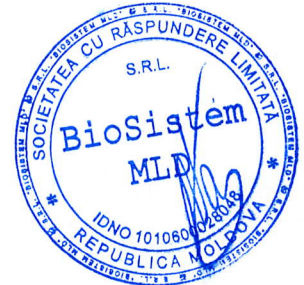
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: İzmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



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



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: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: H.Pylori Ab Test
Brand: TEST IT®
Classification: Professional Use IVD, 98/79/EC
Conformity Assessment Route: Annex III

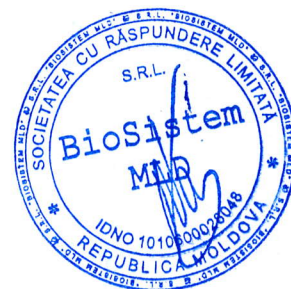
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: İzmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SOKAK NO:2 MENDERES / İZMİR
FABRIKA: İTOB OSB MAH. 10017 SOK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 80 / FAX: 0 232 376 80 40
MENDERES / İZ. 879 009 6209



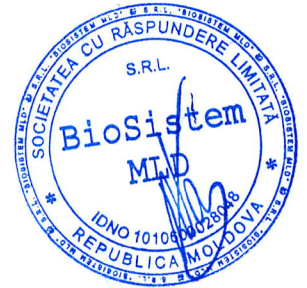
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 21.04.2022
Signature Kartal Yağlıdere
General Manager

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



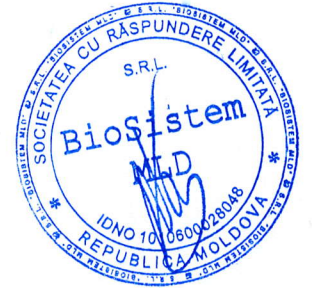
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 04.01.2021
Signature Kartal Yağlıdere
General Manager

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



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

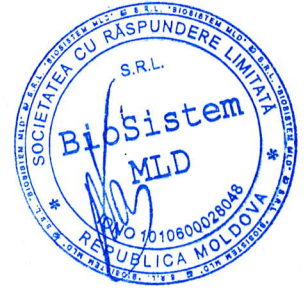
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



TURKLAB
TIBBI MALZ. SAN. VE TIC. 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. 879 099 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®
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.

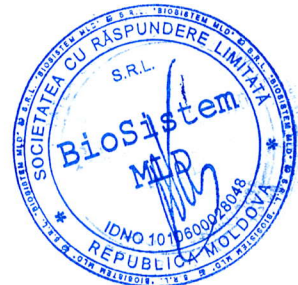
Standards Applied: EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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 MAL.10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAL.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



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

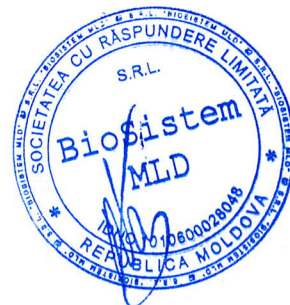
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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 Yağıldere
General Manager



TÜRKLAB
TIBBİ MALZEME 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 00 81- FAX: 0 232 376 00 40
MENDERES V.D. 879 009 6209

CE

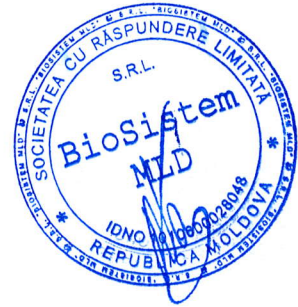
EC DECLARATION OF CONFORMITY

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

Manufacturer: Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - 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



Revision No: 0

Place, Date of Issue: İzmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager

TÜRLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAHALLESİ NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAHALLESİ NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 41 - FAX: 0 232 376 80 40
MENDERES / İZMİR 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: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey
Product: Troponin I Test
Brand: TEST IT®
Classification: Professional Use IVD, 98/79/EC
Conformity Assessment Route: Annex III

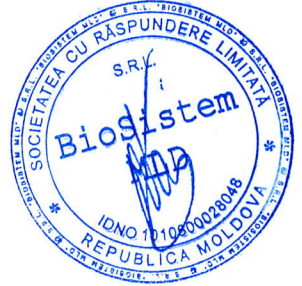
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: İzmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager



TÜRKLAB
TİBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MALZ. SAN. VE TİC. A.Ş. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MALZ. SAN. VE TİC. A.Ş. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 41 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



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

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



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

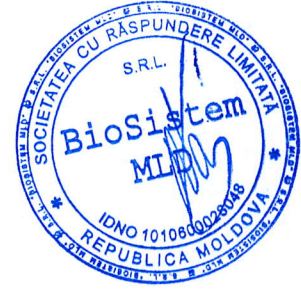
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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



TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: ITOB OSB MAH. 10017 SOKAK NO: 2 TEKELİ - MENDERES / İZMİR
FABRİKA: ITOB OSB MAH. 10017 SOKAK NO: 2 TEKELİ - MENDERES / İZMİR
TEL: 0 232 376 80 87 / 0 232 376 80 80
MENDERES YOLU: 109 5302

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

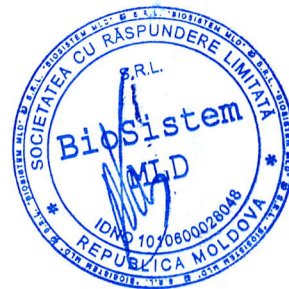
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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



TÜRKLAB
TIBBİ MAL VE CİHAZ VE TİC. A.Ş.
MERKEZ: İTOB OSYU MAH. 10017 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSYU MAH. 10017 SK. NO:9 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



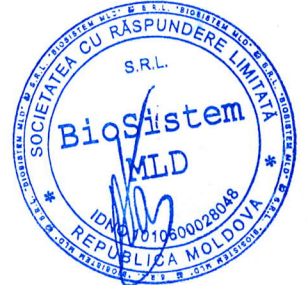
EC DECLARATION OF CONFORMITY

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

Manufacturer: TÜRLAB 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



Revision No/Revision Date: 0

Place, Date of Issue: Izmir, 29.04.2022

Signature Kartal Yağlıdere
General Manager

TÜRLAB
TIBBİ MALZEMELER TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 SOK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 10017 SOK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 60 61 - FAX: 0 232 376 60 40
MENDERES M.D. 879 009 6209



DOC10/01

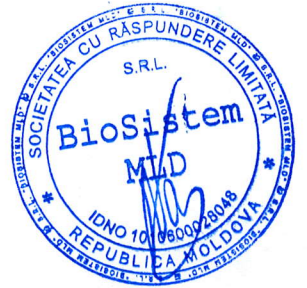
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 20.05.2021
Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MENDERES V.D. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MENDERES V.D. 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

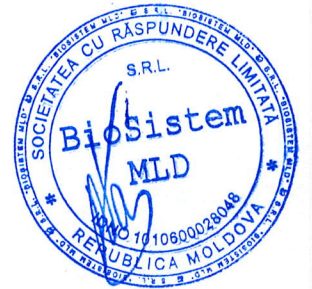
We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

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

Revision No: 0

Place, Date of Issue: Izmir, 04.01.2021

Signature Kartal Yağlıdere
General Manager



TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: ITOB OSB MAH. 10017 SOKAK NO:2 MENDERES / İZMİR
FABRİKA: ITOB OSB MAH. 10017 SOKAK NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 00 - FAX: 0 232 376 80 40
MENDERES Y.D. 879 009 6209



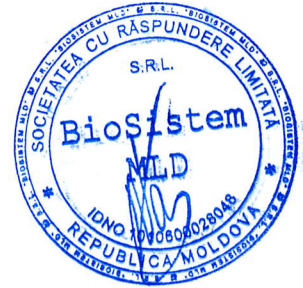
EC DECLARATION OF CONFORMITY

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



Revision No: 0

Place, Date of Issue: Izmir, 02.07.2020

Signature Kartal Yağlıdere
General Manager

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



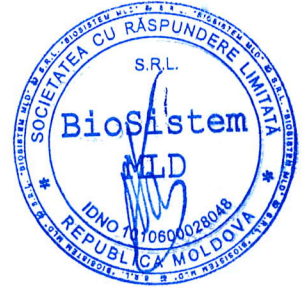
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 02.03.2020

Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB SAN. VE TİC. BÖLGE NO:15 MENDERES-İZMİR
FABRİKA: İTOB OSB SAN. T.0017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



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



Revision No: 0
Place, Date of Issue: Izmir, 02.07.2020

Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:16 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. 0017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 41 - 376 80 40
MENDERES V.D. 879 009 6209

CE

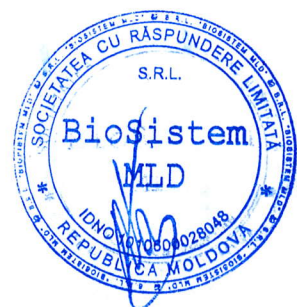
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 21.04.2022

Signature Kartal Yağlıdere
General Manager

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

CE

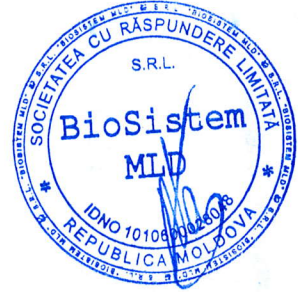
EC DECLARATION OF CONFORMITY

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: 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



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. / SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH. / SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



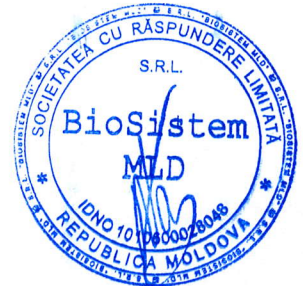
EC DECLARATION OF CONFORMITY

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



Revision No: 0
Place, Date of Issue: Izmir, 21.04.2022
Signature Kartal Yağıldere
General Manager

TÜRKLAB
TIBBI MALZ. SAN. VE TIC. A.Ş.
MERKEZ: İTOB OSB - MAND. 10 / SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB / MAND. 10 / SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

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



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.

阳, 李

Date: 2022.08.12

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
Manager

Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date: 2022.08.29