EC DECLARATION OF CONFORMITY

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

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

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

Standards Applied:

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

Digitally signed by Poiata Vitalie
Date: 2023.11.24 17:24:07 EET
Reason: MoldSign Signature
Location: Moldova

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

Start of CE Marking: 29.08.2008

Revision No: 9

Place, Date of Issue: Izmir, 18.07.2023

Signature

Kartal Yağlıdere
General Manager

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

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

CE 1434

CERTIFICATE

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

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

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

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

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

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

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

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

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

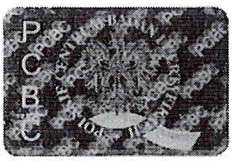
The date of the first issue of the Certificate: 29.08.2008

CE 1434

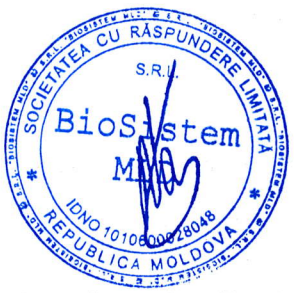
Application No: 56/2019
Module: H7

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

Michał Pachowski, PhD
President



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



CERTIFICATE

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

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

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

in vitro diagnostic medical devices, List A

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

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

Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

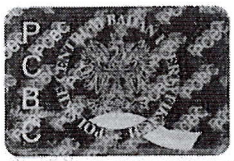
The date of the first issue of the Certificate: 29.08.2008

CE 1434

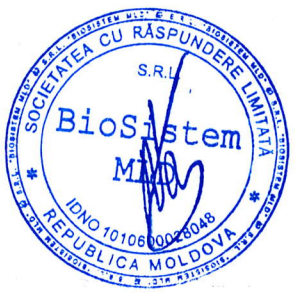
Application No: S6/2019
Module: H6

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

Michał Pachowski, PhD
President



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



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

BM.433.0056.2019/KW/MV/2023/0202

Warsaw, 13.04.2023

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

To Whom it May Concern,

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

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

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

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

Yours Sincerely,

Tomasz Koeber

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

Head of Medical Device
Certification Division

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