



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.

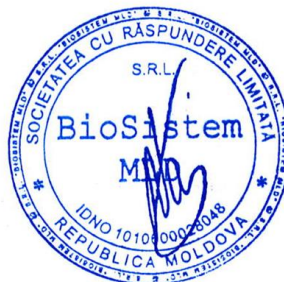
Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

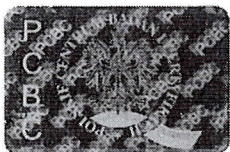
The date of the first issue of the Certificate: 29.08.2008



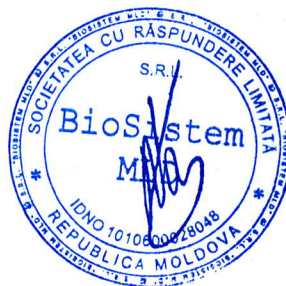
Application No: 56/2019
Module: H7



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.

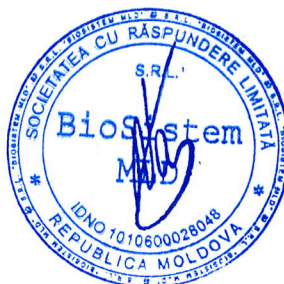
Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

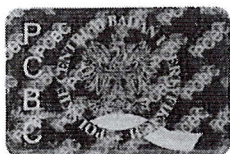
The date of the first issue of the Certificate: 29.08.2008



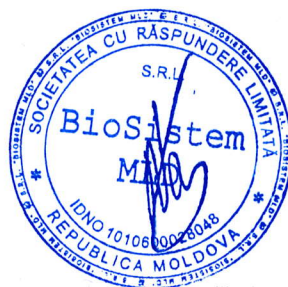
Application No: 56/2019
Module: H6



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.
İTOB 10017 Sokak No: 2,
Tekeli – Menderes İzmir, 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:

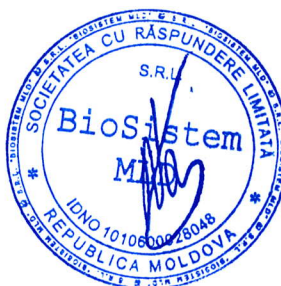
- Info®
- Toyo®
- Rapidan Tester®
- Test It

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,

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

**Head of Medical Device
Certification Division**



CERTIFICATION.
TESTING.
TRAINING.

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
nr 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division

EC DECLARATION OF CONFORMITY

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

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

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

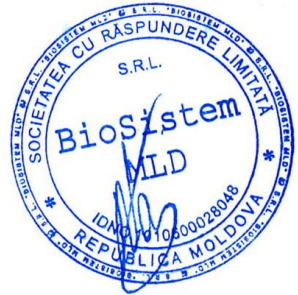
Standards Applied: EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 15223:2016
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002

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

Start of CE Marking: 29.08.2008
Revision No: 9
Place, Date of Issue: Izmir, 18.07.2023

Signature Kartal Yağlıdere
General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAHALLESİ, KAT: 2, MENDERES / İZMİR
PAZARI: İTOB OSB MAHALLESİ, KAT: 2, MENDERES / İZMİR
TEL: 0 232 775 00 61 - FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209



CE 1434