

# 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 Site:** ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey  
**Product:** Anti-HCV Test  
**Brand:** Rapidan® Tester, Toyo®, Info®, Test It®  
**Classification:** Annex II List A, 98/79/EC  
**Conformity Assessment Route:** Annex IV

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

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

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

**Start of CE Marking:** 29.08.2008

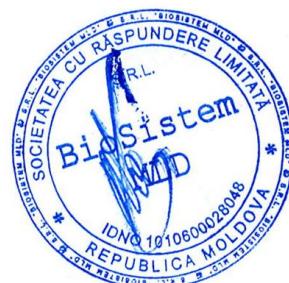
**Revision No:** 8

**Place, Date of Issue:** Izmir, 08.02.2023

**Signature** Kartal Yağlıdere

General Manager

**TURKLAB**  
TİBBİ MALZ. SAN. VE TİC. A.Ş.  
MERKEZ: İTOB 10017 SOKAK NO: 2 TEKELİ - MENDERES / İZMİR  
FİRŞATKA: İTOB 058 MAZLUM 47/5K, NO:2 MENDERES / İZMİR  
TEL: 0 232 376 82 81- FAX: 0 232 376 80 40  
MENSAH: V.D. 879 009 8299



CE 1434



# CERTIFICATE

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

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

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

**TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.**  
**İTOB 10017 Sokak No: 2, Tekeli - Menderes**  
**Izmir, Turkey**

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

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

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

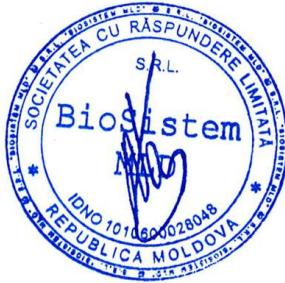
Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

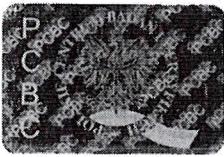
The date of the first issue of the Certificate: 29.08.2008

**CE**  
**1434**

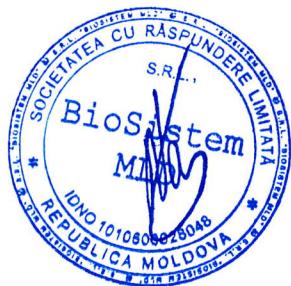
Application No: 58/2019  
Module: H7



  
Michał Pachowski, PhD  
President



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





# CERTIFICATE

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

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.**  
**İTOB 10017 Sokak No: 2, Tekeli - Menderes**  
**Izmir, Turkey**

in vitro diagnostic medical devices, List A

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

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

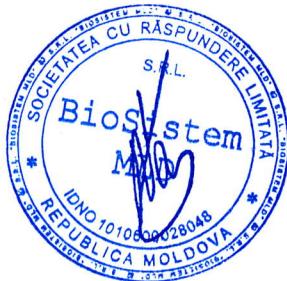
Validity of Certificate: from 29.08.2019 to 28.08.2024

The date of issue of the Certificate: 29.08.2019

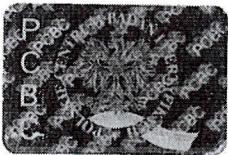
The date of the first issue of the Certificate: 29.08.2008

**CE** 1434

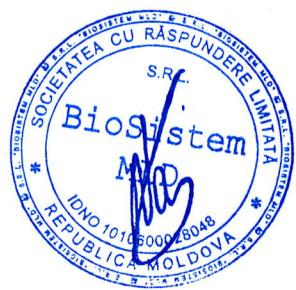
Application No: 58/2019  
Module: H6



  
Michał Pachowski, PhD  
President



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





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

BM.433.0058.2019/KW/MV/2023/0204

Warsaw, 13.04.2023

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

*To Whom it May Concern,*

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

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

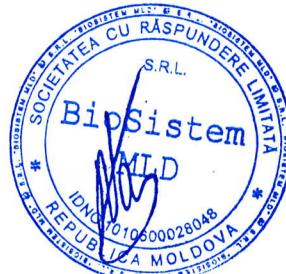
- Info®
- Toyo®
- Rapidan Tester®
- Test It

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

*Yours Sincerely,*

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

**Head of Medical Device  
Certification Division**



CERTIFICATION.  
TESTING.  
TRAINING.

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

NIP 9512063356  
REGON 015276609  
KRS 0000144013

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