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:	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:	4
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md
	General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO: 5 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. 870 009 6209

CE

CERTIFICATE

No. J - 2670/5/2022

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Türkiye

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cells reagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 18.08.2022 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 18.08.2022
Certificate bears a qualified signature.
Warsaw, 19.08.2022

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania

AC 019

IAF Member of Multilateral Recognition Arrangement

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

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. J - 2670/5/2022

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15, Tekeli - Menderes İzmir / Türkiye

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate.

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 18.08.2022
Certificate bears a qualified signature.
Warsaw, 19.08.2022

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

IAF Member of Multilateral Recognition Arrangement

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

CERTIFICATE

No. M - 56/5/2022

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Türkiye

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 18.08.2022 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 18.08.2022
Certificate bears a qualified signature.
Warsaw, 19.08.2022

MEMBER OF IQNET

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

IAF Member of Multilateral Recognition Arrangement

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

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 56/5/2022

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15, Tekeli - Menderes İzmir / Türkiye

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate.

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 18.08.2022
Certificate bears a qualified signature.
Warsaw, 19.08.2022

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