

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: 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: 5

Place, Date of Issue: İzmir, 08.03.2019

Signature Dr. Şahin Yağlıdere, Md
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. 079 009 6209





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



AC 019





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



AC 019





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 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



AC 019





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



AC 019

