



POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. M - 56/7/2024

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
İTOB 10031 Sokak No: 15 35477 Tekeli - Menderes
- İzmir / Türkiye

(certified locations 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), professional use IVD tests**

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 04.01.2024 to 21.12.2026

MEMBER OF



AC 019



Issued under the Contract No. 2897/M/5/2023
Date of certification decision: 04.01.2024
Certificate bears a qualified signature.
Warsaw, 05.01.2024



POLISH CENTRE FOR
TESTING AND CERTIFICATION

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No. M - 56/7/2024

This is to certify that the following Locations:

- İTOB 10031 Sokak No: 15 35477 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**

- İTOB 10017 Sokak No: 2 35477 Tekeli - Menderes - İzmir / Türkiye

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)**

meet the requirements of the standard listed on the certificate.

MEMBER OF



AC 019



Issued under the Contract No. 2897/M/5/2023
Date of certification decision: 04.01.2024
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Warsaw, 05.01.2024