

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 affored 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



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 4

469 Puławska Street, 02-844 Warsaw

phone: +48 22 45 46 200, pcbc@pcbc.gov.pl



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

iTOB 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)



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