



# CERTIFICATE

**No M - 56/4/2020**

**This is to certify that:**

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

**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 22.12.2020 to 21.12.2023**

Issued under the Contract No. 2897/JM/4/2020  
Date of certification decision: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020



AC 019  
QMS



**Member of the Board**



# ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

**No M - 56/4/2020**

This is to certify that the following Location:

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

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: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020



AC 019  
QMS



**Member of the Board**