

CERTIFICATE

**İontek İlaç Tani ve Biyoteknoloji Ürünleri
Araştırma Geliştirme San. ve Ticaret A.Ş.
Sultan Selim Mah. Turan Sok. No: 21/1 Kağıthane
34415 İstanbul, Türkiye**

EN ISO 13485:2016

- **development, manufacturing and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use**
- **marketing and distribution of laboratory supplies and equipment's, molecular genetic kits**

from 15.02.2024 to 04.12.2026



Aleksandra Kostmenia
President

[illegible]

ANNEX TO THE CERTIFICATE

No. M - 55/6/2024

• **Sultan Selim Mah. Turan Sok. No: 21/1 Kağıthane
34415 İstanbul, Türkiye**

- **development and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use**
- **marketing and distribution of laboratory supplies and equipment's, molecular genetic kits**

- **Barış SB. Mah. 5002 Sok. Yeni Teknoloji Binası A Blok 4A/Z07
Gebze 41400 Kocaeli, Türkiye**

- **development, manufacturing and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use**
- **marketing and distribution of laboratory supplies and equipment's, molecular genetic kits**

MEMBER OF



AC 019



Aleksandra Kostmenko
President

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Certificate

PCBC has issued an IQNET recognized certificate that the organization:

**Iontek Ilac Tani ve Biyoteknoloji Ürünleri
Araştırma Geliştirme San. ve Ticaret A.Ş.**

Sultan Selim Mah. Turan Sok. No: 21/1 Kağıthane 34415 İstanbul, Türkiye

(certified locations listed in the Annex to the certificate)

has implemented and maintains a

Medical Devices Management System

for the following scope:

- development, manufacturing and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use
- marketing and distribution of laboratory supplies and equipment's, molecular genetic kits

which fulfils the requirements of the following standard:

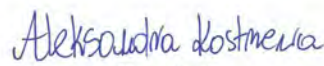
EN ISO 13485:2016

Issued on: 15.02.2024

Expires on: 04.12.2026

Registration Number: PL - M - 55/6/2024


Alex Stoichitoiu
President of IQNET


Aleksandra Kostmeva
President

 **PCBC**

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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MSZT Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** Mexico **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM**
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Annex 1 to IQNET Certificate Number:

M - 55/6/2024

Iontek İlaç Tani ve Biyoteknoloji Ürünleri
Araştırma Geliştirme San. ve Ticaret A.Ş.

Sultan Selim Mah. Turan Sok. No: 21/1 Kağıthane 34415 İstanbul, Türkiye

List of additional locations:

- Sultan Selim Mah. Turan Sok. No: 21/1 Kağıthane 34415 İstanbul, Türkiye
for the following scope:
 - development and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use
 - marketing and distribution of laboratory supplies and equipment's, molecular genetic kits
- Barış SB. Mah. 5002 Sok. Yeni Teknoloji Binası A Blok 4A/Z07 Gebze 41400 Kocaeli, Türkiye
for the following scope:
 - development, manufacturing and sales of in vitro diagnostic medical devices: Real-Time PCR Kits class C and D intended for professional use
 - marketing and distribution of laboratory supplies and equipment's, molecular genetic kits


Alex Stoichitoiu
President of IQNET


Aleksandra Kostmeva
President

 PCBC

This annex is only valid in connection with the original certificate number mentioned above.

IQNET Members*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic
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Colombia ICS Bosnia and Herzegovina INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea LSQA Uruguay MIRTEC Greece
MSZT Hungary Nemko AS Norway NSAI Ireland NYCE México PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM
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