



CERTIFICATE

No. J - 2669/4/2020

This is to certify that:

**İontek İlaç Tanı ve Biyoteknoloji Ürünleri
Araştırma Geliştirme Sanayi ve Ticaret A. Ş.
Sultan Selim Mah. Turan Sok. No.21/1 Kağıthane
34415 İstanbul-TURKEY**

Place of business

**Barış SB Mahallesi 5002 Sokak Yeni Teknoloji Binası A Blok 4A/Z07,
41400 Gebze/Kocaeli, Turkey**

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

- Design, development, manufacturing and distribution of in vitro diagnostics medical devices: List A, List B and not listed, intended for professional use
- Custom oligonucleotide synthesis
- Molecular genetics laboratory services
- Marketing and sales services of laboratory supplies and equipments, molecular genetic kits

The audit carried out by the Polish Centre for 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 10.12.2020 to 04.12.2023

Issued under the Contract No. 2967/JM/4/2020
Date of certification decision: 10.12.2020
Certificate bears a qualified signature.
Warsaw, 28.12.2020



Member of the Board



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

PCBC has issued an IQNet recognized certificate that the organization:

**İontek İlaç Tanı ve Biyoteknoloji Ürünleri
Araştırma Geliştirme Sanayi ve Ticaret A. Ş.
Sultan Selim Mah. Turan Sok. No.21/1 Kağıthane
34415 İstanbul-TURKEY**

Place of business

**Barış SB Mahallesi 5002 Sokak Yeni Teknoloji Binası A Blok 4A/Z07,
41400 Gebze/Kocaeli, Turkey**

has implemented and maintains a
Quality Management System

for the following scope:

- **Design, development, manufacturing and distribution of in vitro diagnostic medical devices: List A, List B and not listed, intended for professional use**
 - **Custom oligonucleotide synthesis**
 - **Molecular genetics laboratory services**
- **Marketing and sales services of laboratory supplies and equipments, molecular genetic kits**

which fulfils the requirements of the following standard:

EN ISO 9001:2015

Issued on: **10.12.2020**

Expires on: **04.12.2023**

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

Registration Number: PL - J - 2669/4/2020



Alex Stoichitoiu
President of IQNet

Member of the Board



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil PONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



CERTIFICATE

No. M - 55/4/2020

This is to certify that:

**İontek İlaç Tanı ve Biyoteknoloji Ürünleri
Araştırma Geliştirme Sanayi ve Ticaret A. Ş.
Sultan Selim Mah. Turan Sok. No.21/1 Kağıthane
34415 İstanbul-TURKEY**

Place of business

**Barış SB Mahallesi 5002 Sokak Yeni Teknoloji Binası A Blok 4A/Z07,
41400 Gebze/Kocaeli, Turkey**

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

- Development, manufacturing and distribution of in vitro diagnostic medical devices: List A, list B and not listed, intended for professional use
- Marketing and sales services of laboratory supplies and equipments, molecular genetic kits

The audit carried out by the Polish Centre for 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 10.12.2020 to 04.12.2023

Issued under the Contract No. 2967/JM/4/2020
Date of certification decision: 10.12.2020
Certificate bears a qualified signature.
Warsaw, 28.12.2020



AC 019
QMS



Member of the Board



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

PCBC has issued an IQNet recognized certificate that the organization:

**İontek İlaç Tanı ve Biyoteknoloji Ürünleri
Araştırma Geliştirme Sanayi ve Ticaret A. Ş.
Sultan Selim Mah. Turan Sok. No.21/1 Kağıthane
34415 İstanbul-TURKEY**

Place of business

**Barış SB Mahallesi 5002 Sokak Yeni Teknoloji Binası A Blok 4A/Z07,
41400 Gebze/Kocaeli, Turkey**

has implemented and maintains a

Medical Devices Management System

for the following scope:

- **Development, manufacturing and distribution of in vitro diagnostic medical devices: List A, list B and not listed, intended for professional use**
- **Marketing and sales services of laboratory supplies and equipments, molecular genetic kits**

which fulfils the requirements of the following standard:

EN ISO 13485:2016

Issued on: **10.12.2020**

Expires on: **04.12.2023**

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

Registration Number: PL - M - 55/4/2020



Alex Stoichitoiu
President of IQNet

Member of the Board



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com