

acreditat pentru  
CERTIFICARE



SR EN ISO/CEI 17021-1:2015  
CERTIFICAT DE ACREDITARE  
SM 004



# C E R T I F I C A T

**SRAC certifică organizația/ certifies the organisation**

## **ROTEST S.R.L.**

*Str. Aeroportului, nr. 2, corp 1, parter, cam. 10, sector 1, București*

**pentru următoarele activități/  
for the following fields of activities**

*Import, depozitare, comercializare, dispozitive medicale de diagnostic in vitro (IVD): Reactivi și produse reactive, calibranți și materiale de control pentru: Chimie Clinică; Imunochimie (Imunologie); Hematologie/ Hemostaza/ Imunohematologie; Microbiologie; Imunologie Infecțioasă; Histologie/Citologie; Testare Genetică. Import, depozitare, comercializare, montare și service echipamente pentru diagnostic in vitro și software. Import, depozitare, comercializare, montare și service dispozitive medicale IVD, altele decât cele specificate anterior*

*Import, storage, sale of in vitro diagnostic medical devices (IVD): Reagents and reagent products, calibrators and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology / Hemostasis / Immunohematology; Microbiology; Infectious Immunology; Histology / Cytology; Genetic Testing. Import, storage, sale, installation and servicing of in vitro diagnostic equipment and software. Import, storage, sale, installation and servicing of IVD medical devices, other than those specified above*

că are implementat și menține un  
**sistem de managementul calității**  
conform condițiilor din standardul

which has implemented and maintains a  
**quality management system**  
which fulfils the requirements of the standard

## **EN ISO 13485:2016**



Valabilitatea certificatului este condiționată de  
efectuarea supravegheților anuale până la data de:



03-  
2023



03-  
2024

nr. certificat/ certificate registration no. **59**  
data inițială a certificării/ initial certification date **23 aprilie 2015**  
data recertificării/ reissuing date **31 martie 2022**  
data ultimei actualizări/ last update -  
valabil până la/ valid until **23 martie 2025** (cu condiția vizării anuale)  
SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București [www.srac.ro](http://www.srac.ro)

Director General  
**Ing. Mihaela Cristea**





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**SRAC** as an IQNet Partner hereby states that the organization:

**ROTEST S.R.L.**

*Str. Aeroportului, nr. 2, corp 1, parter, cam. 10, sector 1, București*

*for the following scope:*

*Import, storage, sale of in vitro diagnostic medical devices (IVD): Reagents and reagent products, calibrators and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology / Hemostasis / Immunohematology; Microbiology; Infectious Immunology; Histology / Cytology; Genetic Testing. Import, storage, sale, installation and servicing of in vitro diagnostic equipment and software. Import, storage, sale, installation and servicing of IVD medical devices, other than those specified above*

*has implemented and maintains a*

*Quality Management System*

*which fulfils the requirements of the following standard:*

**EN ISO 13485 : 2016**

*Issued on: 2022 - 03 - 31*

*First issued on: 2015 - 04 - 23*

*for the validity date, please refer to the original certificate\* issued by SRAC*

**Registration Number: RO - 0059**



*Alex Stoichitoiu*  
President of IQNet

*eng. Mihaela Cristea*  
SRAC General Manager



**IQNet Partners\*\*:**

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

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