



C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

A & A PRO DIAGNOSTIC S.R.L.

Sediul social: Str. Grâului, nr. 19, sector 4, București

Sedii de lucru: B-dul George Coșbuc, nr. 50, sector 5, București;

Calea Rahovei, nr. 185, subsolul imobilului și camerele 1 și 4 la etaj, sector 5, București

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

Import, depozitare, comercializare, instalare, punere în funcțiune, instruire, mentenanță, reparare și verificare: dispozitive medicale de diagnostic in vitro (IVD): analizoare automate și semiautomate pentru chimie clinică și imunoturbidimetrie, hematologie, coagulare, imunologie, electroforeză, electroliți. Import, distribuție, depozitare și comercializare dispozitive medicale de diagnostic in vitro (IVD): reactivi și produse reactive, calibranți și materiale de control pentru: chimie clinică, imunochimie (imunologie), hematologie / hemostază / imunoematologie, microbiologie, imunologie infecțioasă, histologie / citologie, testare genetică, coagulare, electroforeză, electroliți

Import, storage, sale, installation, commissioning, training, maintenance, repairing and checking of: medical in vitro diagnostic medical devices (IVD): automatic and semiautomatic analyzers for clinical chemistry and immunoturbidimetry, hematology, coagulation, immunology, electrophoresis, electrolytes. Import, distribution, storage and sale of in vitro diagnostic medical devices (IVD): reagents and reactive products, calibrators and control materials for: clinical chemistry, immunochemistry (immunology), hematology / haemostasis / imunoematology, microbiology, infectious immunology, histology / cytology, genetic testing, coagulation, electrophoresis, electrolytes

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 supravegerilor anuale până la data de:



09-
2019

09-
2020

nr. certificat/ certificate registration no. **78**

data inițială a certificării/ initial certification date **03 noiembrie 2015**

data recertificării/ reissuing date **11 septembrie 2018**

data ultimei actualizări/ last update -

valabil până la/ valid until **02 noiembrie 2021** (cu condiția vizării anuale)

SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București www.srac.ro

Director General
Ing. Mihaela Cristea





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SRAC as an IQNet Partner hereby states that the organization:

A & A PRO DIAGNOSTIC S.R.L.

Registered Office: Str. Grâului, nr. 19, sector 4, București

Productive Units: B-dul George Coșbuc, nr. 50, sector 5, București;

Calea Rahovei, nr. 185, subsolul imobilului și camerele 1 și 4 la etaj, sector 5, București

for the following scope:

Import, storage, sale, installation, commissioning, training, maintenance, repairing and checking of: medical in vitro diagnostic medical devices (IVD): automatic and semiautomatic analyzers for clinical chemistry and immunoturbidimetry, hematology, coagulation, immunology, electrophoresis, electrolytes. Import, distribution, storage and sale of in vitro diagnostic medical devices (IVD): reagents and reactive products, calibrators and control materials for: clinical chemistry, immunochemistry (immunology), hematology / haemostasis / immunohematology, microbiology, infectious immunology, histology / cytology, genetic testing, coagulation, electrophoresis, electrolytes

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2018 - 09 - 11

First issued on: 2015 - 11 - 03

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

Registration Number: RO - 78



*Alex Stoichitoiu
President of IQNet*

*eng. Mihaela Cristea
SRAC General Manager*



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 FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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

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