

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

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. 183, sector 5, București

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

Import, depozitare, distribuție, instalare, punere în funcțiune, instruire, mentenanță, reparare și verificare dispozitive medicale de diagnostic in vitro (IVD): instrumente de diagnostic in vitro și software. Import, depozitare și distribuție 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; dispozitive medicale IVD altele decât cele specificate anterior: medii de transport; dispozitive medicale neactive, neimplantabile, altele decât cele specificate anterior: măști și mănuși

Import, storage, distribution, installation, commissioning, Training, maintenance, repair and verification of in vitro diagnostic medical devices (IVD): In vitro diagnostic tools and software. Import, storage and distribution of in vitro diagnostic medical devices (IVD): Reagents and reactive products, calibrators and control materials for: Clinical chemistry, immunochemistry (immunology), haematology / haemostase / immunohaematology, microbiology, infectious immunology, histology / cytology, genetic testing; IVD medical devices other than those specified above: Transport media; non-active, non-implantable medical devices other than those specified above: Masks and gloves

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:



10-
2022

10-
2023

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

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valabil până la/ valid until **01 noiembrie 2024** (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. Grăului, nr. 19, sector 4, București

Productive Units: B-dul. George Coșbuc, nr. 50, sector 5, București;
Calea Rahovei, nr. 183, sector 5, București

for the following scope:

Import, storage, distribution, installation, commissioning, Training, maintenance, repair and verification of in vitro diagnostic medical devices (IVD): In vitro diagnostic tools and software. Import, storage and distribution of in vitro diagnostic medical devices (IVD): Reagents and reactive products, calibrators and control materials for: Clinical chemistry, immunochemistry (immunology), haematology / haemostase / immunohaematology, microbiology, infectious immunology, histology / cytology, genetic testing; IVD medical devices other than those specified above: Transport media; non-active, non-implantable medical devices other than those specified above: Masks and gloves

has implemented and maintains a
Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2021 - 10 - 20

First issued on: 2015 - 11 - 03

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

Registration Number: RO - 0078



Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager



IQNet Partners:**

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Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia
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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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