

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

DAC - SPECTROMED S.R.L.

Sediul social: Str. Nicolae Testemițanu, 37, municipiul Chișinău, Republica Moldova

Sediul de lucru: Bd. Cuza-Vodă, 5, bloc 1, sec. Botanică, municipiul Chișinău, Republica Moldova

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

Fabricare și comercializare de dispozitive medicale de diagnostic in vitro: seturi de reactivi (reagenți), calibranți pentru chimie clinică, imunologie, hemostază, dozatoare automate. Comercializare pentru dispozitive medicale de diagnostic in vitro: reactivi pentru imunohematologie, imunologie infecțioasă. Comercializare, instalare și service dispozitive medicale IVD: echipamente pentru laborator (analizoare pentru biochimie, hematologie, analiză urină; turbidimetrie, etuve cu caldură uscată)

Manufacturing and trade of in vitro diagnostic medical devices: sets of reagents (reagents), calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Trade for in vitro diagnostic medical devices: reagents for immunohematology, infectious immunology. Trade, installation and service IVD medical devices: laboratory equipment (biochemistry analyzers, hematology, urine analysis, turbidimetry, dry heat ovens)

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:



nr. certificat/ certificate registration no. **27**

data inițială a certificării/ initial certification date **28 noiembrie 2012**

data recertificării/ reissuing date **24 noiembrie 2021**

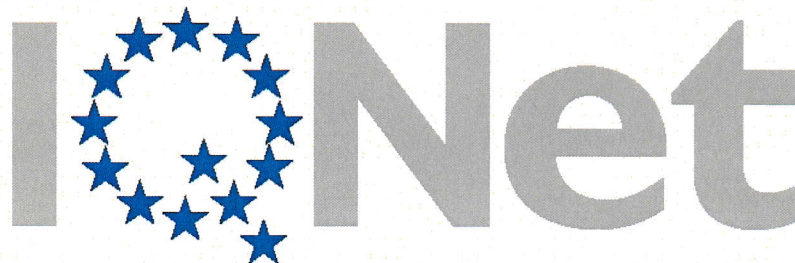
data ultimei actualizări/ last update -

valabil până la/ valid until **25 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:

DAC - SPECTROMED S.R.L.

*Registered Office: Str. Nicolae Testemițanu, 37, municipiul Chișinău,
Republica Moldova*

*Productive Unit: Bd. Cuza-Vodă, 5, bloc 1, sec. Botanică, municipiul Chișinău,
Republica Moldova*

for the following scope:

*Manufacturing and trade of in vitro diagnostic medical devices: sets of reagents (reagents),
calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Trade for
in vitro diagnostic medical devices: reagents for imunohematologie, infectious immunology.
Trade, installation and service IVD medical devices: laboratory equipment (biochemistry
analyzers, hematology, urine analysis, turbidimetry, dry heat ovens)*

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2021 - 11 - 24

First issued on: 2012 - 11 - 28

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

Registration Number: RO - 0027



Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager



IQNet Partners:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISO 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 Vincotte Belgium YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISO, 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