



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 organization

DAC - SPECTROMED S.R.L.

Sediul social: Str. Nicolae Testemitanu, 37, Chișinău, Republica Moldova

fără activități certificate/ without certified activities

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

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

Fabricare și distribuție dispozitive medicale de diagnostic in vitro: seturi de reactivi (reagenți), calibranți pentru chimie clinică, imunologie, hemostază, dozatoare automate. Import și distribuție dispozitive medicale de diagnostic in vitro: reactivi pentru imunohematologie, imunologie infecțioasă. Import, distribuție, instalare și service instrumente de diagnostic in vitro și software

Manufacture and distribution of in vitro diagnostic medical devices: sets of reactives (reagents), calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Import and distribution of in vitro diagnostic medical devices: reactives for immunohematology, infectious immunology. Import, distribution, installation and service of in vitro diagnostic instruments and software

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

SR EN ISO 13485:2016



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



11-
2025

11-
2026

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

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

data recertificării/ recertification date **01 noiembrie 2024**

data ultimei actualizări/ last update -

valabil până la/ valid until **27 noiembrie 2027** (cu condiția vizării anuale)

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

Director General
Ing. Mihaela Cristea



Certificate

SRAC has issued an IQNET recognized certificate that the organization:

DAC - SPECTROMED S.R.L.

Registered Office: Str. Nicolae Testemitanu, 37, Chişinău, Republica Moldova
without certified scope

Productive Unit: Bd. Cuza-Vodă, 5, bloc 1, sec. Botanica, Chişinău, Republica Moldova

has implemented and maintains a
Quality Management System

for the following scope:

Manufacture and distribution of in vitro diagnostic medical devices: sets of reactives (reagents), calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Import and distribution of in vitro diagnostic medical devices: reactives for immunohematology, infectious immunology. Import, distribution, installation and service of in vitro diagnostic instruments and software

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: **2024 - 11 - 01**
First issued on: **2012 - 11 - 28**
Expires on: **2027 - 11 - 27**

Registration Number: RO – 0027



Alex Stoichitoiu
President of IQNET



eng. Mihaela Cristea
SRAC General Manager



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

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