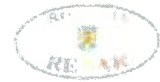


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SR EN ISO/CEI 17021-1 2015
CERTIFICAT DE ACREDITARE
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C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

DAC - SPECTROMED S.R.L.

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

Sediul de lucru: Str. Cuza-Vodă str. 5/1, 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 imuno hematologie, imunologie infecțioasă. Comercializare, instalare și service dispozitive medicale IVD: echipamente pentru laborator (analizoare pentru biochimie, hematologie, analiză urină; turbidimetrie, etuve cu căldură uscată)

Manufacturing and trade of in vitro diagnostic medical devices: sets of reactivities (reagents), calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Trade for in vitro diagnostic medical devices: reactivities for imuno hematologie, 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 25 septembrie 2018
data ultimei actualizări/ last update 18 octombrie 2019
valabil până la/ valid until 26 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:

DAC - SPECTROMED S.R.L.

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

Productive Unit: Str. Cuza-Vodă str. 5/1, Chișinău, Republica Moldova

for the following scope:

Manufacturing and trade of in vitro diagnostic medical devices: sets of reactives (reagents), calibrators for clinical chemistry, immunology, hemostasis, automatic dispensers. Trade for in vitro diagnostic medical devices: reactives 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: 2019 - 10 - 18

First issued on: 2012 - 11 - 28

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

Registration Number: RO - 27



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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