



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SRAC as an IQNet Partner hereby states that the organization:

DAC - SPECTROMED S.R.L.

Registered Office: Str. Armenească, nr. 47, ap. 64, Chişinău, Republica Moldova

Productive Unit: Str. Cuza-Vodă str. 5/1, Chişinău, 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: 2018 - 09 - 25

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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C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

DAC - SPECTROMED S.R.L.

Sediul social: Str. Armenească, nr. 47, ap. 64, 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), calibranti 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 căldură uscată)

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 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:



09-
2019

09-
2020



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 -

Director General
Ing. Mihaela Cristea