



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 imunoematologie, 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

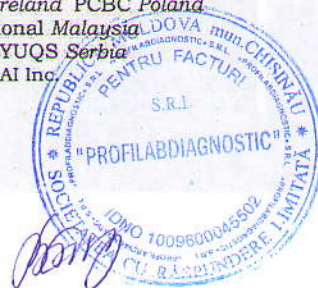
eng. Mihaela Cristea  
SRAC General Manager



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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), 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 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:



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**