

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**

**HEMAT - ROM S.R.L.**

*Intrarea Țintea, nr. 6, sector 1, București*

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

*Import, distribuție dispozitive medicale neactive: Dispozitive medicale generale neactive, neimplantabile: dispozitive medicale neactive pentru dezinfectare, curățare, clătire; Dispozitive pentru îngrijirea rănilor: alte dispozitive medicale pentru îngrijirea rănilor (vată, plasturi, tampoane nazofaringiene); Dispozitive medicale neactive, altele decât cele specificate anterior (măști medicale, garouri, apăsătoare limbă, saci pericol biologic, saci deșeurilor patologice, mănuși). Import, distribuție dispozitive medicale de diagnostic in vitro (IVD): Reactivi și produse reactive, calibrări și materiale de control pentru: Chimie Clinică; Imunochimie (Imunologie); Hematologie / Hemostază / Imunohematologie; Microbiologie; Imunologie Infecțioasă; Histologie / Citologie; Testare Genetică. Dispozitive medicale IVD, altele decât cele specificate anterior (vacutainere, tuburi recoltare, coprorecoltare, eprubete, pipete, vârfuri de pipete, lame și lamele de microscop, ace pentru recoltare, plăci). Import, distribuție, instalare, instruire și mentenanță dispozitive medicale de diagnostic in vitro (IVD): Instrumente de diagnostic in vitro și software*

*Import, distribution of non-active medical devices: General non-active, non-implantable medical devices: non-active medical devices for disinfection, cleaning, rinsing; Devices for wound care: other medical devices for wound care (cotton wool, patches, nasopharyngeal swabs); Non-active medical devices other than those specified above (medical masks, tourniquets, tongue depressors, biological hazard bags, pathological waste bags, gloves). Import, distribution of in vitro diagnostic medical devices (IVD): Reagents and reactive products, calibrations and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology / Hemostasis / Immunohematology; Microbiology; Infectious Immunology; Histology / Cytology; Genetic Testing. IVD medical devices other than those specified above (vacutainers, collection tubes, coprorecollectors, test tubes, pipettes, pipette tips, glass slides, collection needles, boards). Import, distribution, installation, training and maintenance of in vitro diagnostic medical devices (IVD): 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

**EN ISO 13485:2016**

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



10-  
2023

10-  
2024



nr. certificat/ certificate registration no. **180**  
data inițială a certificării/ initial certification date **13 octombrie 2022**  
data recertificării/ reissuing date -  
data ultimei actualizări/ last update -  
valabil până la/ valid until **12 octombrie 2025** (cu condiția vizării anuale)  
SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București [www.srac.ro](http://www.srac.ro)

Director General  
**Ing. Mihaela Cristea**





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

**SRAC** as an IQNet Partner hereby states that the organization:

**HEMAT - ROM S.R.L.**

*Intrarea Țintea, nr. 6, sector 1, București*

*for the following scope:*

*Import, distribution of non-active medical devices: General non-active, non-implantable medical devices: non-active medical devices for disinfection, cleaning, rinsing; Devices for wound care: other medical devices for wound care (cotton wool, patches, nasopharyngeal swabs); Non-active medical devices other than those specified above (medical masks, tourniquets, tongue depressors, biological hazard bags, pathological waste bags, gloves). Import, distribution of in vitro diagnostic medical devices (IVD): Reagents and reactive products, calibrations and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology / Hemostasis / Immunohematology; Microbiology; Infectious Immunology; Histology / Cytology; Genetic Testing. IVD medical devices other than those specified above (vacutainers, collection tubes, coprorecoltors, test tubes, pipettes, pipette tips, glass slides, collection needles, boards). Import, distribution, installation, training and maintenance of in vitro diagnostic medical devices (IVD):  
In vitro diagnostic instruments and software*

*has implemented and maintains a  
Quality Management System*

*which fulfils the requirements of the following standard:*

**EN ISO 13485 : 2016**

*Issued on: 2022 - 10 - 13*

*First issued on: 2022 - 10 - 13*

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

**Registration Number: RO - 0180**



*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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