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 organizaţia/ certifies the organization

HEMAT - ROM SRL

Sediul social: Intrarea Ţintea, nr. 6, sector 1, Bucureşti

cu activităţile prezentate în anexă
with the activities as listed in the annex

că are implementat şi menţine un
sistem de managementul calităţii
conform condiţiilor din standardul

which has implemented and maintains a
quality management system
which fulfils the requirements of the standard

SR EN ISO 13485:2016

Dispozitivele medicale care fac obiectul domeniului de certificare sunt cele acoperite de Avizul de funcţionare în vigoare, emis de ANMDMR/
The medical devices subject to the scope of certification are those covered by the valid Operating Authorization, issued by the ANMDMR

Valabilitatea certificatului este condiţionată de efectuarea supravegherilor anuale până la data de: 10-2026 10-2027

nr. certificat/ certificate registration no. **180**
data iniţială a certificării/ initial certification date **13 octombrie 2022**
data recertificării/ recertification date **10 octombrie 2025**
data ultimei actualizări/ last update **-**
valabil până la/ valid until **12 octombrie 2028** (cu condiţia vizării anuale)
SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, Bucureşti www.srac.ro

Director General
Ing. Mihaela Cristea

A N E X Ă
C E R T I F I C A T

HEMAT - ROM SRL

Intrarea Ţintea, nr. 6, sector 1, Bucureşti

pentru următoarele activităţi/
for the following fields of activities

Import, distribuţie dispozitive medicale neactive: Dispozitive pentru îngrijirea rănilor: alte dispozitive medicale pentru îngrijirea rănilor (vată, plasturi, tampoane nazofaringiene); Dispozitive medicale neactive, altele decât cele specificate anterior (măşti medicale, garouri, apăsătoare limbă, saci pericol biologici, saci deşeuri patologice, mănuşi).
Import, distribuţie dispozitive medicale active (neimplantabile) altele decât cele specificate anterior: frigidere şi congelatoare medicale.
Import, distribuţie dispozitive medicale de diagnostic in vitro (IVD): Reactivi şi produse reactive, calibranţi şi materiale de control pentru: Chimie Clinică; Imunochimie (Imunologie); Hematologie/Hemostază/Imunohematologie; Microbiologie; Imunologie Infecţioasă; Histologie/Citologie; Testare Genetică. Dispozitive medicale IVD, altele decât cele specificate anterior (vacutainere, tuburi recoltare, coprorecoltoare, eprubete, pipete, vârfuri de pipete, lame şi lamele de microscop, ace pentru recoltare, plăci).
Import, distribuţie, instalare, mentenanţă (întreţinere, reparare) dispozitive medicale de diagnostic in vitro (IVD): Instrumente de diagnostic in vitro şi software. Instruire utilizatori finali pentru dispozitivele medicale menţionate

Import and distribution of non-active medical devices: Wound care devices: other medical devices for wound care (cotton wool, plasters, nasopharyngeal swabs); Other non-active medical devices not previously specified (medical masks, tourniquets, tongue depressors, biohazard bags, pathological waste bags, gloves).
Import and distribution of active (non-implantable) medical devices not previously specified: Medical refrigerators and freezers.
Import and distribution of in vitro diagnostic (IVD) medical devices: Reagents and reactive products, calibrators, and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology/Hemostasis/Immunohematology; Microbiology; Infectious Immunology; Histology/Cytology; Genetic Testing. Other IVD medical devices not previously specified (vacutainers, blood collection tubes, stool sample containers, test tubes, pipettes, pipette tips, microscope slides and cover slips, sampling needles, plates).
Import, distribution, installation, and maintenance (servicing and repair) of in vitro diagnostic (IVD) medical devices: In vitro diagnostic instruments and software. End-user training for the above-mentioned medical devices

IQNET

Building trust together.

Certificate

SRAC has issued an IQNET recognized certificate that the organization:

HEMAT - ROM SRL

Registered Office: Intrarea Țintea, nr. 6, sector 1, Bucureşti

has implemented and maintains a
Quality Management System

with the activities as listed in the annex

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on:	**2025 - 10 - 10**
First issued on:	**2022 - 10 - 13**
Expires on:	**2028 - 10 - 12**

Registration **Number: RO - 0180**

Alex Stoichitoiu
President of IQNET

eng. Mihaela Cristea
SRAC General Manager

SR AC

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

IQNET Members*:
AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic **Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS** International Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

*The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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Annex 1 of 1 to IQNET Certificate Number

RO - 0180

HEMAT - ROM SRL

Intrarea Țintea, nr. 6, sector 1, București

for the following scope

Import and distribution of non-active medical devices: Wound care devices: other medical devices for wound care (cotton wool, plasters, nasopharyngeal swabs); Other non-active medical devices not previously specified (medical masks, tourniquets, tongue depressors, biohazard bags, pathological waste bags, gloves).
Import and distribution of active (non-implantable) medical devices not previously specified: Medical refrigerators and freezers.
Import and distribution of in vitro diagnostic (IVD) medical devices: Reagents and reactive products, calibrators, and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Hematology/Hemostasis/Immunohematology; Microbiology; Infectious Immunology; Histology/Cytology; Genetic Testing. Other IVD medical devices not previously specified (vacutainers, blood collection tubes, stool sample containers, test tubes, pipettes, pipette tips, microscope slides and cover slips, sampling needles, plates).
Import, distribution, installation, and maintenance (servicing and repair) of in vitro diagnostic (IVD) medical devices: In vitro diagnostic instruments and software. End-user training for the above-mentioned medical devices

This annex is only valid in connection with the original certificate number mentioned above.