

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 organization

OPTIMED SRL

Str. Lungă, nr. 112, camera 1, Brașov, jud. Brașov

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

Import și distribuție de dispozitive medicale neactive/dispozitive medicale generale neactive, neimplantabile: dispozitive neactive oftalmologice, dispozitive medicale neactive pentru dezinfectare, curățare, clătire, instrumente medicale neactive. Import, distribuție, instalare și mentenanță pentru: dispozitive medicale active neimplantabile/dispozitive medicale active generale: dispozitive chirurgicale active, dispozitive oftalmologice active, dispozitive active pentru poziționarea și transportul pacientului, software; dispozitive pentru imagistică: dispozitive pe bază de raze non-ionizante

Import and distribution of non-active medical devices / general non-active medical devices, non-implantable: non-active ophthalmic devices, non-active medical devices for disinfection, cleaning, rinsing, non-active medical instruments. Import, distribution, installation and maintenance for: non-implantable active medical devices / general active medical devices: active surgical devices, active ophthalmic devices, active patient positioning and transport devices, software; imaging devices: devices based on non-ionizing rays

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

SR EN ISO 13485:2016



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



07-
2026

07-
2027

nr. certificat/ certificate registration no. **112**

data inițială a certificării/ initial certification date **25 iulie 2019**

data recertificării/ recertification date **21 iulie 2025**

data ultimei actualizări/ last update -

valabil până la/ valid until **24 iulie 2028** (cu condiția vizării anuale)

SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București www.srac.ro

Director General
Ing. Mihaela Cristea

Certificate

SRAC has issued an IQNET recognized certificate that the organization:

OPTIMED SRL

Str. Lungă, nr. 112, camera 1, Braşov, jud. Braşov

has implemented and maintains a
Quality Management System

for the following scope:

Import and distribution of non-active medical devices / general non-active medical devices, non-implantable: non-active ophthalmic devices, non-active medical devices for disinfection, cleaning, rinsing, non-active medical instruments. Import, distribution, installation and maintenance for: non-implantable active medical devices / general active medical devices: active surgical devices, active ophthalmic devices, active patient positioning and transport devices, software; imaging devices: devices based on non-ionizing rays

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2025 - 07 - 21
First issued on: 2019 - 07 - 25
Expires on: 2028 - 07 - 24

Registration Number: RO – 0112



Alex Stoichitoiu
President of IQNET



eng. Mihaela Cristea
SRAC General Manager



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 JOA 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