



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

CICOR MEDTEC BUCHAREST SRL

Sediul social: B-dul. 1 Decembrie 1918, nr. 1G, et. 1, ap. CORP 2, sector 3, București

*cu activitățile prezentate în anexă
with the activities as listed in the annex*

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:



05-
2025

05-
2026

nr. certificat/ certificate registration no. **24**

data inițială a certificării/ initial certification date **23 mai 2012**

data recertificării/ recertification date **20 mai 2024**

data ultimei actualizări/ last update **20 ianuarie 2025**

valabil până la/ valid until **22 mai 2027** (cu condiția vizării anuale)

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

Director General
Ing. Mihaela Cristea



A N E X Ă C E R T I F I C A T



CICOR MEDTEC BUCHAREST SRL

B-dul. 1 Decembrie 1918, nr. 1G, et. 1, ap. CORP 2, sector 3, București

pentru următoarele activități/ for the following fields of activities

Proiectare, dezvoltare, asamblare, testare, punere în funcțiune, management de proiect, realizare soft la comandă, activități de inginerie și consultanță tehnică pentru: Dispozitive medicale active (neimplantabile): Dispozitive medicale active generale: Componente pentru dispozitive respiratorii; Dispozitive pentru stimulare sau inhibare; Dispozitive chirurgicale active; Dispozitive active pentru dezinfectare și sterilizare; Dispozitive active de reabilitare și proteze active; Componente pentru dispozitive active pentru poziționarea și transportul pacientului; Software, inclusiv dezvoltarea software-ului pentru dispozitive medicale; Componente pentru sisteme de alimentare cu gaze medicale și părți ale acestora. Dispozitive pentru imagistică: Componente pentru dispozitive pe bază de raze non-ionizante; Dispozitive de monitorizare: Dispozitive de monitorizare a parametrilor fiziologici nonvitali; Dispozitive de monitorizare a parametrilor fiziologici vitali. Dispozitive pentru terapia cu radiații și termoterapie: Componente pentru dispozitive pe bază de radiații ne-ionizante; Componente pentru dispozitive pentru hipertermie/hipotermie; Componente pentru dispozitive medicale active (neimplantabile) altele decât cele specificate anterior: Dispozitiv de monitorizare a tusei - CPT1. Dispozitive medicale active implantabile: Dispozitive medicale active implantabile generale: Dispozitive medicale active implantabile pentru stimulare/ inhibare; Dispozitive medicale active implantabile care substituiesc sau înlocuiesc funcțiile organelor; Componente pentru dispozitive medicale implantabile, altele decât cele specificate anterior: Dispozitiv Medical - Înlocuire laringe - POT1. Dispozitive medicale de diagnostic in vitro (IVD): Instrumente de diagnostic in vitro și software. Dispozitive care încorporează/utilizează substanțe specifice/tehnologii: Componente pentru dispozitive medicale care utilizează micromecanica. Piese de schimb sau servicii: Componente: componente electrice, elemente de fixare și piese din plastic turnat; Subansambluri: subansambluri electronice, subansambluri mecanice, realizate la desene și / sau instrucțiuni de lucru; Alte servicii: Servicii legate de dispozitive medicale. Consultanță

Design, development, assembly, testing, commissioning, project management, custom software creation, engineering activities and technical consultancy, for: Active medical devices (non-implantable): General active medical devices: Components for respiratory devices; Devices for stimulation or inhibition; Active surgical devices; Active devices for disinfection and sterilization; Active rehabilitation devices and active prostheses; Components for active devices for patient positioning and transport; Software, including software development for medical devices; Components for medical gas supply systems and their parts. Imaging devices: Components for devices based on non-ionizing rays; Monitoring devices: Devices for monitoring non-vital physiological parameters; Devices for monitoring vital physiological parameters. Devices for radiation therapy and thermotherapy: Components for devices based on non-ionizing radiation; Components for hyperthermia/hypothermia devices; Components for active medical devices (non-implantable) other than those specified above: Cough monitoring device - CPT1. Active implantable medical devices: General implantable active medical devices: Active implantable medical devices for stimulation/inhibition; Active implantable medical devices that substitute or replace organ functions; Components for implantable medical devices, other than those previously specified: Medical Device -Laryngeal Replacement - POT1 In vitro diagnostic medical devices (IVD): In vitro diagnostic tools and software. Devices that incorporate/use specific substances/technologies: Components for medical devices using micromechanics. Spare parts or services: Components: electrical components, fasteners and molded plastic parts; Subassemblies: electronic subassemblies, mechanical subassemblies, made according to drawings and/or work instructions; Other services: Services related to medical devices. Consulting

Certificate

SRAC has issued an IQNET recognized certificate that the organization:

CICOR MEDTEC BUCHAREST SRL

Registered Office: B-dul. 1 Decembrie 1918, nr. 1G, et. 1, ap. CORP 2, sector 3, București

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 - 01 - 20**
First issued on: **2012 - 05 - 23**
Expires on: **2027 - 05 - 22**

Registration Number: RO - 0024



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*:

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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

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Annex 1 of 1 to IQNET Certificate Number

RO - 0024

CICOR MEDTEC BUCHAREST SRL

B-dul. 1 Decembrie 1918, nr. 1G, et. 1, ap. CORP 2, sector 3, București

for the following scope:

Design, development, assembly, testing, commissioning, project management, custom software creation, engineering activities and technical consultancy, for: Active medical devices (non-implantable): General active medical devices: Components for respiratory devices; Devices for stimulation or inhibition; Active surgical devices; Active devices for disinfection and sterilization; Active rehabilitation devices and active prostheses; Components for active devices for patient positioning and transport; Software, including software development for medical devices; Components for medical gas supply systems and their parts. Imaging devices: Components for devices based on non-ionizing rays; Monitoring devices: Devices for monitoring non-vital physiological parameters; Devices for monitoring vital physiological parameters. Devices for radiation therapy and thermotherapy: Components for devices based on non-ionizing radiation; Components for hyperthermia/hypothermia devices; Components for active medical devices (non-implantable) other than those specified above: Cough monitoring device - CPT1. Active implantable medical devices: General implantable active medical devices: Active implantable medical devices for stimulation/inhibition; Active implantable medical devices that substitute or replace organ functions; Components for implantable medical devices, other than those previously specified: Medical Device -Laryngeal Replacement - POT1 In vitro diagnostic medical devices (IVD): In vitro diagnostic tools and software. Devices that incorporate/use specific substances/technologies: Components for medical devices using micromechanics. Spare parts or services: Components: electrical components, fasteners and molded plastic parts; Subassemblies: electronic subassemblies, mechanical subassemblies, made according to drawings and/or work instructions; Other services: Services related to medical devices, Consulting

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This annex is only valid in connection with the original certificate number mentioned above.
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IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic
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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**
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