

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*

## **EVOLUTION MEDTEC S.R.L.**

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

*cu sediile de lucru și activitățile prezentate în anexă  
with the productive units and 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-  
2022

05-  
2023

nr. certificat/ certificate registration no. **24**  
data inițială a certificării/ initial certification date **23 mai 2012**  
data recertificării/ reissuing date **24 mai 2021**  
data ultimei actualizări/ last update -  
valabil până la/ valid until **20 mai 2024** (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**

# A N E X Ă C E R T I F I C A T



## EVOLUTION MEDTEC S.R.L.

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

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

Proiectare, dezvoltare, asamblare, punere în funcțiune, marketing, management de proiect, testări, realizare soft la comandă, editarea a altor produse software și consultanță tehnică pentru: Dispozitive medicale neactive (Dispozitive medicale generale neactive, neimplantabile: Dispozitive neactive pentru injecții, infuzii, transfuzii și dializă; Dispozitive medicale neimplantabile (Dispozitive medicale active generale: Dispozitive pentru circulația extra-corporală, infuzii și hemaferază; Dispozitive respiratorii, dispozitive care includ camere hiperbarice pentru terapia cu oxigen, anestezia inhalatorie; Dispozitive pentru stimulare sau inhibare; Dispozitive chirurgicale active; Dispozitive oftalmologice active; Dispozitive dentare active; Dispozitive active pentru dezinfectare și sterilizare; Dispozitive active de reabilitare și proteze active; Dispozitive active pentru poziționarea și transportul pacientului; Dispozitive active pentru fertilizarea in vitro (IVF) și tehnologii reproductive asistate (ART); Software; Sisteme de alimentare cu gaze medicale și părți ale acestora; Dispozitive pentru imagistică: Dispozitive pe bază de raze ionizante; 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: Dispozitive pe bază de radiații ionizante; Dispozitive pe bază de radiații ne-ionizante; Dispozitive medicale active (neimplantabile) altele decât cele specificate anterior); Dispozitive medicale active implantabile (Dispozitive medicale active implantabile generale: Dispozitive medicale active implantabile pentru stimulare / inhibare; Dispozitive medicale active implantabile pentru administrarea medicamentelor și a altor substanțe; Dispozitive medicale active implantabile care substituiesc sau înlocuiesc funcțiile organelor); Dispozitive medicale implantabile, altele decât cele specificate anterior); Dispozitive medicale de diagnostic in vitro (IVD); Instrumente de diagnostic in vitro și software; Dispozitive medicale IVD, altele decât cele specificate anterior; Dispozitive care încorporează / utilizează substanțe specifice / tehnologii (Dispozitive medicale care încorporează substanțe medicale; Dispozitive medicale care încorporează sânge uman; Dispozitive medicale care utilizează micromecanică; Dispozitive medicale care încorporează sau utilizează substanțe / tehnologii / elemente specifice, altele decât cele specificate mai sus); Componente; Subansamble; Alte servicii

# A N E X Ă C E R T I F I C A T



## **EVOLUTION MEDTEC S.R.L.**

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

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

*Design, development, assembly, commissioning, marketing, project management, testing, custom software production, editing of other software products and technical consultancy for: Non-active medical devices (Non-active, non-implantable general medical devices: Non-active devices for injections, infusions, transfusions and dialysis; Non-implantable medical devices (General active medical devices: Devices for extra-corporeal circulation, infusions and hemapheresis; Respiratory devices, devices that include hyperbaric chambers for oxygen therapy, inhaled anesthesia; Devices for stimulation or inhibition; Active surgical devices; Active ophthalmological devices; Active dental devices; Active devices for disinfection and sterilisation; Active rehabilitation devices and active prostheses; Active devices for patient positioning and transport; Active in vitro fertilisation (IVF) and assisted reproductive technologies (ART); Software; Medical gas supply systems and parts thereof; Imaging devices: Ionizing ray-based devices; Non-ionizing ray-based devices; Monitoring devices: Devices for monitoring nonvital physiological parameters; Devices for monitoring vital physiological parameters; Devices for radiation therapy and thermotherapy: Ionizing radiation-based devices; Non-ionizing radiation-based devices; Active (non-implantable) medical devices other than those specified above); Implantable Active Medical Devices (General Implantable Active Medical Devices: Implantable active medical devices for stimulation / inhibition; Implantable active medical devices for the administration of medicinal and other substances; Implantable active medical devices that replace or replace organ functions); Implantable medical devices other than those specified above); In vitro diagnostic medical devices (IVD); In vitro diagnostic tools and software; IVD medical devices other than those specified above; Devices that incorporate/use specific substances/technologies (Medical devices that incorporate medical substances; Medical devices incorporating human blood; Medical devices using micromechanics; Medical devices that incorporate or use substances/technologies/specific elements other than those specified above); Components; Subassemblies; Other services*



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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

## **EVOLUTION MEDTEC S.R.L.**

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

*with the productive units and activities as listed in the annex*

*has implemented and maintains a*

*Quality Management System*

*which fulfils the requirements of the following standard:*

### **EN ISO 13485 : 2016**

*Issued on: 2021 - 05 - 24*

*First issued on: 2012 - 05 - 23*

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

**Registration Number: RO - 0024**



*Alex Stoichitoiu*  
President of IQNet

*eng. Mihaela Cristea*  
SRAC General Manager



#### **IQNet Partners\*\*:**

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 FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland  
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia  
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

\*\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

## **Annex to Certificate Number : RO - 0024**

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### ***EVOLUTION MEDTEC S.R.L.***

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

*for the following scope:*

*Design, development, assembly, commissioning, marketing, project management, testing, custom software production, editing of other software products and technical consultancy for: Non-active medical devices (Non-active, non-implantable general medical devices: Non-active devices for injections, infusions, transfusions and dialysis; Non-implantable medical devices (General active medical devices: Devices for extra-corporeal circulation, infusions and hemapheresis; Respiratory devices, devices that include hyperbaric chambers for oxygen therapy, inhaled anesthesia; Devices for stimulation or inhibition; Active surgical devices; Active ophthalmological devices; Active dental devices; Active devices for disinfection and sterilisation; Active rehabilitation devices and active prostheses; Active devices for patient positioning and transport; Active in vitro fertilisation (IVF) and assisted reproductive technologies (ART); Software; Medical gas supply systems and parts thereof; Imaging devices: Ionizing ray-based devices; Non-ionizing ray-based devices; Monitoring devices: Devices for monitoring nonvital physiological parameters; Devices for monitoring vital physiological parameters; Devices for radiation therapy and thermotherapy: Ionizing radiation-based devices; Non-ionizing radiation-based devices; Active (non-implantable) medical devices other than those specified above); Implantable Active Medical Devices (General Implantable Active Medical Devices: Implantable active medical devices for stimulation / inhibition; Implantable active medical devices for the administration of medicinal and other substances; Implantable active medical devices that replace or replace organ functions); Implantable medical devices other than those specified above); In vitro diagnostic medical devices (IVD); In vitro diagnostic tools and software; IVD medical devices other than those specified above; Devices that incorporate/use specific substances/technologies (Medical devices that incorporate medical substances; Medical devices incorporating human blood; Medical devices using micromechanics; Medical devices that incorporate or use substances/technologies/specific elements other than those specified above); Components; Subassemblies; Other services*