



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

SELF CARE MEDICAL SRL

Sediul social: Str. Pipera Tunari, nr. 51, parter, Birou, Voluntari, jud. Ilfov

Sediul de lucru: Str. Avram Iancu, nr. 54B, parter, Otopeni, jud. Ilfov

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

Import și distribuție: dispozitive medicale neactive, altele decât cele specificate anterior: plasturi termici împotriva durerilor, dispozitive medicale pentru igienă personală (diverse branduri); dispozitive medicale IVD, altele decât cele specificate anterior: IVD pentru auto-testare (diverse branduri). Servicii de ambalare și distribuție: dispozitive medicale neactive, altele decât cele specificate anterior: plasturi termici împotriva durerilor; dispozitive medicale IVD, altele decât cele specificate anterior: IVD pentru auto-testare

Import and distribution: non-active medical devices other than those specified above: thermal pain patches, medical devices for personal hygiene (various brands); IVD medical devices other than those previously specified: IVD for self-testing (various brands). Packaging and distribution services: non-active medical devices other than those specified above: thermal pain patches; IVD medical devices other than those specified above: IVD for self-testing

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-
2024

07-
2025

nr. certificat/ certificate registration no. **127**

data inițială a certificării/ initial certification date **08 iulie 2020**

data recertificării/ reissuing date **07 iulie 2023**

data ultimei actualizări/ last update -

valabil până la/ valid until **07 iulie 2026** (cu condiția vizării anuale)

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

Director General
Ing. Mihaela Cristea





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SRAC as an IQNet Partner hereby states that the organization:

SELF CARE MEDICAL SRL

Registered Office: Str. Pipera Tunari, nr. 51, parter, Birou, Voluntari, jud. Ilfov

Productive Unit: Str. Avram Iancu, nr. 54B, parter, Otopeni, jud. Ilfov

for the following scope:

Import and distribution: non-active medical devices other than those specified above: thermal pain patches, medical devices for personal hygiene (various brands); IVD medical devices other than those previously specified: IVD for self-testing (various brands). Packaging and distribution services: non-active medical devices other than those specified above: thermal pain patches; IVD medical devices other than those specified above: IVD for self-testing

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2023 - 07 - 07

First issued on: 2020 - 07 - 08

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

Registration Number: RO - 0127



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