



C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

P.S. ELETTRONICA S.R.L.

Via Nolana II, Traversa 20, Pompei(NA), CAP 80045, Italy

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

*Cercetare, dezvoltare, proiectare și fabricare pentru instrumente și software de diagnosticare în vitro.
Dispozitive medicale de diagnosticare în vitro pentru produse de diagnosticare: Reactivi și produse reactive, calibratori și materiale de control pentru chimie clinică, imunochimie (imunologie), hematologie, microbiologie, imunologie infecțioasă, histologie / citologie, testare genetică, instrumente de diagnostic în vitro și software. Instalare și service*

*Research, development, design and manufacture for in vitro diagnostic instruments and software.
Merchandising (trading) in vitro diagnostic medical devices: Reagents and reagent products, calibrators, and control materials for clinical chemistry, immunochemistry (immunology), haematology, microbiology, infectious immunology, histology / cytology, genetic testing, in vitro diagnostic instruments and software. Instalation and service*

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

EN ISO 13485:2016



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



nr. certificat/ certificate registration no. **92**
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valabil până la/ valid until **11 mai 2020** (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:

P.S. ELETTRONICA S.R.L.

Via Nolana II, Traversa 20, Pompei(NA), CAP 80045, Italy

for the following scope:

Research, development, design and manufacture for in vitro diagnostic instruments and software. Merchandising (trading) in vitro diagnostic medical devices: Reagents and reagent products, calibrators, and control materials for clinical chemistry, immunochemistry (imunology), haematology, microbiology, infectious immunology, histology / cytology, genetic testing, in vitro diagnostic instruments and software. Instalation and service

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2018 - 07 - 02

First issued on: 2017 - 05 - 12

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

Registration Number: RO - 92



Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager



IQNet Partners:**

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

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