



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**

**THERANOVA PROTEZARE SRL**

Sediul social: Str. Eroul Necunoscut, nr. 2, Oradea, jud. Bihor  
**fără activități certificate/ without certified activities**

Sediul de lucru: Str. General Gheorghe Mărdărescu, Parcul Industrial EUROBUSINESS I,  
Oradea, jud. Bihor

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

*Proiectare și fabricație dispozitive medicale neactive ortopedice și de reabilitare: saci colectori pentru stomii; proteze și ortoze; proiectare și fabricație proteze active cu acționare mioelectrică; distribuție dispozitive medicale neactive și active ortopedice și de reabilitare*

*Design and manufacture of non-active orthopedic and rehabilitation medical devices: collector bags for ostomy; prostheses and orthoses; design and manufacture of active prostheses with myoelectric actuation; distribution of orthopedic and rehabilitation non-active and active medical devices*

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:



02-  
2025

02-  
2026

nr. certificat/ certificate registration no. **148**  
data inițială a certificării/ initial certification date **26 februarie 2021**  
data recertificării/ recertification date **19 februarie 2024**  
data ultimei actualizări/ last update -  
valabil până la/ valid until **25 februarie 2027** (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**



# Certificate

SRAC has issued an IQNET recognized certificate that the organization:

## **THERANOVA PROTEZARE SRL**

**Registered Office: Str. Eroul Necunoscut, nr. 2, Oradea, jud. Bihor**  
without certified scope

**Productive Unit: Str. General Gheorghe Mărdărescu, Parcul Industrial EUROBUSINESS I, Oradea, jud. Bihor**

has implemented and maintains a  
**Quality Management System**

for the following scope:

**Design and manufacture of non-active orthopedic and rehabilitation medical devices: collector bags for ostomy; prostheses and orthoses; design and manufacture of active prostheses with myoelectric actuation; distribution of orthopedic and rehabilitation non-active and active medical devices**

which fulfils the requirements of the following standard:

**EN ISO 13485 : 2016**

Issued on: **2024 - 02 - 19**

First issued on: **2021 - 02 - 26**

Expires on: **2027 - 02 - 25**

**Registration Number: RO – 0148**



**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.

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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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