

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**

## **BIOFARM SA**

*Sediul social: Str. Logofătul Tăutu, nr. 99, sector 3, București*

*Sediul de lucru: Str. Drumul Gura Bădicului, nr. 202-232, sector 3, București*

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

*Proiectare, fabricație, testare, distribuție dispozitive medicale neactive altele decât cele specificate anterior (spray din sfera ORL, soluții uz extern). Proiectare, testare dispozitive medicale generale neactive neimplantabile: dispozitive medicale neactive pentru ingerare, dispozitive medicale neactive, altele decât cele specificate anterior (soluții de uz extern). Distribuție dispozitive medicale generale neactive neimplantabile: dispozitive medicale neactive pentru ingerare, dispozitive medicale neactive, altele decât cele specificate anterior (forme topice)*

*Design, manufacturing, testing, distribution of non-active medical devices other than those specified above (spray from the ENT sphere, solutions for external use). Design, testing of non-implantable general non-active medical devices: non-active medical devices for ingestion, non-active medical devices other than those specified above (solutions for external use). Distribution of general non-active non-implantable medical devices: non-active medical devices for ingestion, non-active medical devices other than those specified above (topical forms)*

**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:



03-  
2024

03-  
2025

nr. certificat/ certificate registration no. **187**  
data inițială a certificării/ initial certification date **17 martie 2023**  
data recertificării/ reissuing date -  
data ultimei actualizări/ last update -  
valabil până la/ valid until **16 martie 2026** (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**





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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

## **BIOFARM SA**

Registered Office: Str. Logofătul Tăutu, nr. 99, sector 3, București  
Productive Unit: Str. Drumul Gura Bădicului, nr. 202-232, sector 3, București

for the following scope:

*Design, manufacturing, testing, distribution of non-active medical devices other than those specified above (spray from the ENT sphere, solutions for external use). Design, testing of non-implantable general non-active medical devices: non-active medical devices for ingestion, non-active medical devices other than those specified above (solutions for external use). Distribution of general non-active non-implantable medical devices: non-active medical devices for ingestion, non-active medical devices other than those specified above (topical forms)*

has implemented and maintains a

**Quality Management System**

which fulfils the requirements of the following standard:

**EN ISO 13485 : 2016**

Issued on: 2023 - 03 - 17

First issued on: 2023 - 03 - 17

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

Registration Number: RO - 0187



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)