

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

BIOTEHNOS S.A.

Str. Gorunului, nr. 3-5, oraș Otopeni, jud. Ilfov

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

Fabricarea preparatelor farmaceutice - fabricație parțială: operații de recepție, prelevare probe, depozitare, distribuție, transport materii prime, ambalaje și produs finit, ambalare secundară și eliberarea seriei de fabricație pentru produse sterile (forme lichide dozate parenterale volume mici preparate aseptice) și produse nesterile - semisolid. Comerț cu ridicata al produselor farmaceutice. Cercetare dezvoltare în biotehnologie. Activități de testări și analize tehnice - chimice, biochimice, biologice și microbiologice în domeniul industriei farmaceutice și al suplimentelor nutriționale

Manufacture of pharmaceutical preparations - partial production: operations of reception, sampling, storage, distribution, transport of raw materials, packaging and finished products, secondary packaging and batch number release for sterile products (liquid forms dosed - parenteral small volumes prepared aseptically) and products sterile - semisolid. Wholesale of pharmaceutical products. Research and development in biotechnology. Activities of testing and technical analysis - chemical, biochemical, biological and microbiological in the pharmaceutical industry and nutritional supplements

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 9001:2015 (ISO 9001:2015)



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



01-
2022

01-
2023

nr. certificat/ certificate registration no. **10689**
data inițială a certificării/ initial certification date **29 aprilie 2016**
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data ultimei actualizări/ last update -
valabil până la/ valid until **10 ianuarie 2024** (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:

BIOTEHNOS S.A.

Str. Gorunului, nr. 3-5, oraş Otopeni, jud. Ilfov

for the following scope:

Manufacture of pharmaceutical preparations - partial production: operations of reception, sampling, storage, distribution, transport of raw materials, packaging and finished products, secondary packaging and batch number release for sterile products (liquid forms dosed - parenteral small volumes prepared aseptically) and products sterile - semisolid. Wholesale of pharmaceutical products. Research and development in biotechnology. Activities of testing and technical analysis - chemical, biochemical, biological and microbiological in the pharmaceutical industry and nutritional supplements

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

ISO 9001 : 2015

Issued on: 2021 - 01 - 13

First issued on: 2016 - 04 - 29

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

Registration Number: RO - 10689



Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager



IQNet Partners:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
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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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