



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 SA

Str. Gorunului, nr. 3-5, 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 - semisolide. 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 supravegheșilor anuale până la data de:



01-
2026

nr. certificat/ certificate registration no. **10689**

data inițială a certificării/ initial certification date **29 aprilie 2016**

data recertificării/ recertification date ***19 ianuarie 2024**

data ultimei actualizări/ last update -

valabil până la/ valid until **18 ianuarie 2027** (cu condiția vizării anuale)

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

Director General
Ing. Mihaela Cristea

Certificate

SRAC has issued an IQNET recognized certificate that the organization:

BIOTEHNOS SA

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

has implemented and maintains a
Quality Management System

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

which fulfils the requirements of the following standard:

ISO 9001 : 2015

Issued on: 2024 - 01 - 19
First issued on: 2016 - 04 - 29
Expires on: 2027 - 01 - 18

Registration Number: RO - 10689



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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