

BSP PHARMACEUTICALS S.P.A.

IT - 04013 LATINA SCALO (LT) - VIA APPIA KM 65,561

NEI SEGUENTI SITI / IN THE FOLLOWING SITES

IT - 04013 LATINA SCALO (LT) - VIA APPIA KM 65,561

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE SICUREZZA CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A SAFETY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI ISO 45001:2018

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES


SETTORE
CODE **IAF 13**

VEDASI ALLEGATO/SEE ANNEX

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELATIVE ANNEX

PRIMA EMISSIONE
FIRST ISSUE **03/12/2013**
DATA DELIBERA
DECISION DATE **05/08/2021**
DATA SCADENZA
EXPIRY DATE **07/07/2022**
EMISSIONE CORRENTE
ISSUE DATE **05/08/2021**


CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY

BSP PHARMACEUTICALS S.P.A.

For information concerning the validity of the certificate, you can visit the site www.certquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.

ATTIVITA' / ACTIVITIES


Sviluppo e produzione per conto terzi di specialità farmaceutiche antitumorali iniettabili, prodotte in flaconi in forma liquida e liofilizzata mediante processi di pesatura, dissoluzione, filtrazione, riempimento, liofilizzazione, ispezione e confezionamento.

Sviluppo e produzione per conto terzi di specialità farmaceutiche antitumorali orali prodotte in forma di capsule di gelatina rigida riempite con liquidi o polveri, compresse rivestite e non rivestite, mediante processi di pesatura, setacciatura, dissoluzione, miscelazione, granulazione, essiccamento, ripartizione, depolverazione, filmatura, ispezione e confezionamento.

Development and manufacturing of injectable antineoplastic pharmaceuticals products for third parties (CMO Contract Manufacturing Operations), in liquid and Lyophilized vials through dispensing, dissolution, filtration, filling, lyophilization, visual inspection and packaging, Development and manufacturing of oral antineoplastic pharmaceuticals products for third parties (CMO Contract Manufacturing Operations), in capsules, tablets and coated tablets, by using several processes of dispensing, meshing, dissolution, blending, granulation, drying, filling, tableting, dedusting, coating, visual inspection and packaging.

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE FIRST ISSUE	03/12/2013
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®



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.

has issued an IQNet recognised certificate that the organization:

BSP PHARMACEUTICALS S.P.A.

IT - 04013 LATINA SCALO (LT) - VIA APPIA KM 65,561

for the following scope

See *annex*

has implemented and maintains a

Safety Management System

which fulfills the requirements of the following standard

UNI ISO 45001:2018

Issued on: **2021-08-05**

First issued on: **2013-12-03**

Expires on: **2022-07-07**

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

Registration number: **IT-133558**



Alex Stoichitoiu
President of IQNET



Ing. Mario Romersi
President of CISQ

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 EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNet Certificate Number IT-133558

BSP PHARMACEUTICALS S.P.A.

Field of scope

Development and manufacturing of injectable antineoplastic pharmaceuticals products for third parties (CMO Contract Manufacturing Operations), in liquid and Lyophilized vials through dispensing, dissolution, filtration, filling, lyophilization, visual inspection and packaging, Development and manufacturing of oral antineoplastic pharmaceuticals products for third parties (CMO Contract Manufacturing Operations), in capsules, tablets and coated tablets, by using several processes of dispensing, meshing, dissolution, blending, granulation, drying, filling, tableting, dedusting, coating, visual inspection and packaging.

This annex is only valid in connection with the above-mentioned certificate.