

# ANNEX TO CERTIFICATE

No. 42016650



## Statni ustav pro kontrolu leciv

Srobarova 49/48 100 41 Praha 10, Vinohrady, Czech Republic

Standard

## ISO 9001:2015

Certified activity

Performance of state administration - State Institute for Drug Control.

For processes:

Surveillance over manufacture and development of pharmaceuticals

Surveillance over distributors and intermediaries of medicinal products

Surveillance over the quality of pharmaceuticals on the market through laboratory analyses based on predefined projects

Official Control Authority Batch Release

Surveillance in the area of preparation, dispensing and sale of pharmaceuticals

Marketing authorisation of medicinal products

Vigilance system of medical devices

Price and reimbursement regulation

Laboratory control of medicines and excipients on request from other Institute department or other government public authorities

Pharmacovigilance

Borderline products assessment - medicinal products

Clinical trials of human medicinal products

Regulation of advertising of medicinal products

Enforcement

Quality defects

Surveillance over human tissues and cells biological material processing

On-site inspection of persons handling medical devices

Clinical trials of medical devices

Medical cannabis agenda

Registration of persons and notification of medical devices

Expert Activity Coordination

Borderline products assessment -medical devices

Reimbursement of Medical Devices

Regulation of advertising of medical devices and in vitro diagnostic medical devices

Opinion on an active substance that is an integral part of a medical device

### List of certified operational sites/branches/companies (7)

#### Stará 25, 620 00 Brno

Certified activity has the same extent as headquarters activity

#### Benešovská 40/2538, 101 00 Praha 10

Certified activity has the same extent as headquarters activity

#### B. Němcové 54, 370 87 České Budějovice

Certified activity has the same extent as headquarters activity

#### Klicperova 9, 321 00 Plzeň

Certified activity has the same extent as headquarters activity

#### Resslova 745, 500 01 Hradec Králové

Certified activity has the same extent as headquarters activity

#### Tř. 17. Listopadu 1790, 708 52 Ostrava - Poruba

Certified activity has the same extent as headquarters activity

Verification code: **C75B745D-7F0**

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**Křížkovského 3, 779 00 Olomouc**

Certified activity has the same extent as headquarters activity

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The certificate has been issued under No. **42016650** for the registration period from 01 December 2023 to 30 November 2026.



Approved by



Printed by



**THIS ANNEX IS NOT VALID WITHOUT MAIN CERTIFICATE**

Verification code: **C75B745D-7F0**

Check the validity using this code at [www.ll-c.info](http://www.ll-c.info)

LL-C (Certification) Czech Republic a.s. | Pobrezni 620/3, 186 00 Praha 8