

ANNEX TO CERTIFICATE

No. 42013543



Státní ústav pro kontrolu léčiv

Šrobárova 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 medical devices at the workplaces of healthcare providers premises, vendors, services, distributors, importers and producers

Clinical trials of medical devices

Medical cannabis agenda

Registration of persons and notification of medical devices

Expert Activity Coordination Department

Borderline products assessment - medical devices

Reimbursement of medical devices

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

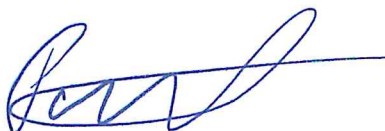
Tř. 17. Listopadu 1790, 708 52 Ostrava - Poruba

Certified activity has the same extent as headquarters activity

Křížkovského 3, 779 00 Olomouc

Certified activity has the same extent as headquarters activity

The certificate has been issued under No. 42013543 for the registration period from 01 December 2020 to 30 November 2023.



Approved by



Printed by



THIS ANNEX IS NOT VALID WITHOUT MAIN CERTIFICATE

Verification code: **B59837C7-F11**

Check the validity using this code at www.ll-c.info

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