



ČESKÁ SPOLEČNOST PRO JAKOST, z.s.
(CZECH SOCIETY FOR QUALITY)

Management Systems Certification Body accredited by Český institut pro akreditaci, o.p.s.
(Czech Accreditation Institute) under registration number 3081

based on the accreditation issues

CERTIFICATE

of compliance of the Quality Management System with the requirements of

ČSN EN ISO 9001:2009

to company

Státní ústav pro kontrolu léčiv
organizační složka státu

Šrobárova 48, 100 41 Praha 10, Czech Republic; Company ID: 0023817

Scope:

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; batch release of defined medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals; 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; Clinical trials on human medicinal products pharmaceuticals; 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.

Above stated activities are carried out in the establishments included in the Appendix which forms an inseparable part of the Certificate.

Certificate registration number: 307/QMS/2016/AJ

Date of the first certification: 08 December 2008

Valid from: 07 June 2016

Valid to: 30 November 2017

Head of the Certification Body Management Systems and Products:
Ing. Petr Koten



The certified company is subject to surveillance by Česká společnost pro jakost, z.s. (Czech Society for Quality). In the case of finding serious non-conformity with requirements of ČSN EN ISO 9001:2009 the certificate effectiveness may be suspended or cancelled.

This is a translation. In case there is a dispute concerning the interpretation the original version of the certificate in the Czech language shall prevail.

Place of issue: Novotného lávka 200/5, Staré Město, 110 00 Praha



Appendix to Certificate No. 307/QMS/2016/AJ

Establishments included in certification including scope

Order Number	Names and addresses of establishments included in certification	Scope
1.	Šrobárova 48, 100 41 – Vihohrady (headquarters)	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; Batch release of defined medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals; Authorisation of medicinal products; 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; Clinical trials on human medicinal products pharmaceuticals; Regulation of advertising of medicinal products; Enforcement; Quality defects; Surveillance over human tissues and cells biological material processing.
2.	Benešovská 40/2538, 101 00 Praha 10	Vigilance system of medical devices; Price and reimbursement regulation; On-site inspection of medical devices at the workplaces of healthcare providers' premises, vendors, services, distributors, importers and producers. Clinical trials of medical devices.
3.	B. Němcové 54, 370 87 České Budějovice	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals.
4.	Klicperova 9, 320 00 Plzeň	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals.
5.	Resslova 745, 500 01 Hradec Králové	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals.
6.	Tř. 17. listopadu 1790, 708 52 Ostrava	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals.
7.	Křížkovského 3, 779 00 Olomouc	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals.
8.	Stará 25, 602 00 Brno	Surveillance over distributors and intermediaries of medicinal products; Surveillance in the area of preparation, dispensing and sale of pharmaceuticals; Price and reimbursement regulation.

Date: 05 May 2017

This annex replaces the annex to the Certificate from 07 June 2016 unabridged.

Head of the Certification Body Management Systems and Products: Ing. Petr Koten


