

CERTIFIKAČNÍ ORGÁN CSQ-CERT PŘI ČESKÉ SPOLEČNOSTI PRO JAKOST

Certification body CSQ-CERT accredited according to the ČSN EN ISO/IEC 17021:2011 by The Czech Accreditation Institute (Českým institutem pro akreditaci, o.p.s.) under registration number 3081 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 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 and clinical trials 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.

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/2014/AJ Date of the first certification: 08 December 2008

Valid from: 01 December 2014 Valid to: 30 November 2017

Head of the Certification Centre Management Systems and Products:

Ing. Eliška Michálková

The certified company is subject to surveillance by the certification body CSQ-CERT. 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: CSQ-CERT, Novotného lávka 5, 116 68 Prague 1



