



CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Státní ústav pro kontrolu léčiv
Prague
Czech Republic**

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 9001:2008

The Quality Management System is applicable to:

Surveillance over manufacturers of medicinal products, 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 medical products, surveillance in the area of preparation, dispensing and sale of pharmaceuticals, authorisation of medicinal products, borderline products assessment, authorisation of clinical trials of pharmaceuticals, surveillance over medical devices use, price and reimbursement regulation, validation of marketing authorisation applications and of price reimbursement of medicinal products, pharmacovigilance and providing information on safety of medicinal products and enforcement and regulation of advertising of medicinal products.

Approval

Certificate No: PRA 6001045

Original Approval: 8 December 2008

Current Certificate: 8 December 2008

Certificate Expiry: 7 December 2011


Issued by: Lloyd's Register EMEA, Prague office,
for and on behalf of Lloyd's Register Quality Assurance Limited



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This document is subject to the provision on the reverse.

Táborská 31, 140 00 Prague 4, Czech Republic CZ61378721

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.

The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001.

Macro Revision 13

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