

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

Erba Lachema s.r.o. Karásek 2219/1d 621 00 Brno **Czech Republic**

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

ISO 9001:2008 ISO 13485:2003

EN ISO 9001:2008

EN ISO 13485:2012

ČSN EN ISO 9001:2009 ČSN EN ISO 13485:2012

The Quality Management System is applicable to:

Design, development and production of in vitro diagnostics medical devices according to own and customer' requirements.

This certificate forms part of the approval identified by certificate number PRA 0003914.

Approval

Original ISO 9001 Approval: 30 January 1998

Certificate No: PRA 0003914/B

Original ISO 13485 Approval: 30 January 1998

Current Certificate: 1 December 2015

Certificate Expiry: 14 September 2018

Issued by: Lloyd's Register EMEA, Prague office,

for and on behalf of Lloyd's Register Quality Assurance Limited

