

Certificate of Approval

This is to certify that the Management System of:

Erba Lachema s.r.o.

Karásek 2219/1d, 621 00 Brno, Czech Republic

has been approved by LRQA to the following standards:

ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe Issued by: Lloyd's Register EMEA for and on behalf of: Lloyd's Register Quality Assurance Limited This certificate forms part of the approval identified by approval number: 0052600

Current issue date: 2 December 2018 Expiry date: 1 December 2021 Certificate identity number: 10151048 Original approval(s): ISO 13485 – 30 January 1998

Approval number(s): ISO 13485 - 0052600-002

The scope of this approval is applicable to:

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





Lloyd's Register Group Limited, its affiliates and subsidiaries, including Lloyd's Register Quality Assurance Limited (LRQA), and their respective officers, employees or agents are, individually and collectively, referred to in this clause as 'Lloyd's Register', Lloyd's Register assumes no responsibility and shall not be liable to any person for any loss, damage or expense caused by reliance on the information or advice in this document or howsoever provised, unless that person has signed a contract with the relevant Lloyd's Register emitty for the provision of this information or advice and in that case any responsibility in liability is exclusively on the terms and conditions set out in that contract. Issued by: Lloyd's Register EMEA, Taborska 31, 140 00 Prague 4, Czech Republic for and on behalf of: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom