CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

ERBA Diagnostics Mannheim GmbH
Mallaustrasse 69-73
68219 Mannheim
Germany

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 is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

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

Approval
Certificate No: PRA 0003914/A

Original ISO 9001 Approval: 25 May 2011

Original ISO 13485 Approval: 25 May 2011

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

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MANAGEMENT
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001

CERTIFICATE SCHEDULE

ERBA Diagnostics Mannheim GmbH
Mallaustrasse 69-73
68219 Mannheim
Germany

Head Office:
ERBA Diagnostics Mannheim GmbH
Mallaustrasse 69-73
68219 Mannheim
Germany

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

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

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

Approval
Certificate No: PRA 0003914/A

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