

Certificate of Approval

This is to certify that the Management System of:

TestLine Clinical Diagnostics s.r.o.

Křižíkova 188/68, 612 00 Brno - Královo Pole, Czech Republic

has been approved by LRQA to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 – 0053053, ISO 9001 – 0053054

The scope of this approval is applicable to:

ISO 13485:2016

Design, development, production, distribution and service of in vitro diagnostics. Distribution of medical device class I.

ISO 9001:2015

Design, development, production, distribution and service of products based on biological material.



Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



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