Current issue date: Expiry date: Certificate identity number: 1 December 2020 30 November 2023 10309823 Original approval(s): ISO 13485 - 30 November 2004 ISO 9001 - 27 November 2002

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 Lloyd's Register 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 North Europe

Issued by: Lloyd's Register EMEA

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



001

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 provided, unless that person has signed a contract with the relevant Lloyd's Register entity for the provision of this information or advice and in that case any responsibility or liability is exclusively on the terms and conditions set out in that contract. Issued by: Lloyd's Register EMEA, Táborská 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