3EC® international

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

TestLine Clinical Diagnostics s.r.o.

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

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURE, DISTRIBUTION AND SERVICE OF IN VITRO DIAGNOSTIC MEDICAL DEVICES: REAGENTS AND REACTION PRODUCTS, CALIBRATORS AND CONTROL MATERIALS FOR IMMUNOCHEMISTRY (IMMUNOLOGY), MICROBIOLOGY, INFECTIOUS IMMUNOLOGY, IN VITRO DIAGNOSTIC DEVICES AND SW, IVD MD OTHER

Certificate No.: M-0485/23 **Date of issuance: December 8th, 2023** **Original date of approval: December 11th, 2020**

This certificate is valid from **December 11th, 2023** to **December 10th, 2026** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA