



CERTIFICATE

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

TestLine Clinical Diagnostics s.r.o.

Křižikova 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-0485/20

Date of issuance: December 11th, 2020

Original date of approval: December 11th, 2020

This certificate is valid from December 11th, 2020 to December 10th, 2023 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 Tomič 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.