



CERTIFICATE

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

Apiro Diagnostics Kft.

Liget út 3/2, HU-2040 Budaörs, Hungary



*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 AND DEVELOPMENT, PRODUCTION, QUALITY CONTROL,
STORAGE AND DISTRIBUTION OF IN-VITRO DIAGNOSTIC MEDICAL DEVICES
AND CONSUMABLES FOR WHOLE-BLOOD COAGULATION**

Certificate No.: M-0602/25

Date of issuance: October 7th, 2025

Original date of approval: October 7th, 2025

This certificate is valid from October 7th, 2025 to October 6th, 2028 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 Tomín 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.