3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2025-IVDR/QS-007/A

Apiro Diagnostics Kft.

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

SRN No.: HU-MF-000043501

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended confirms, that quality management system of in vitro diagnostic medical device:

Product type: Haemostasis reagents - other (EMDN W01030299) & Control plasma for haemostasis (EMDN W0103020702)
For details, see Annex I
Intended purpose: Annex II
IVD MD class C
(detailed list is stated in the annex(es) if applicable)
meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the Technical Documentation Assessment Report No. IVDR036_2024 from 23.07.2025, Performance Evaluation Assessment Report No. IVDR036_2024 from 2025-07-21 and Audit Report No. SK-0829/25 from 2025-09-30. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned in vitro diagnostic medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **2026-01-13**
Valid until: **2030-10-07**
First issue: **2025-10-07**
Revision: **01**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-01-13

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-007/A

issued for the company

Apiro Diagnostics Kft.

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

List of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

Product type	Trade Name	REF
Haemostasis reagents - other (EMDN W01030299)	TPA	1021EU
	IN	1031EU
	HI	1041EU
	AP	1051EU
	FIB	1061EU
	RVV	1071EU
	EX	1081EU
Control plasma for haemostasis (EMDN W0103020702)	QC1	2011EU
	QC2	2021EU

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-01-13
Valid until 2030-10-07

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-007/A

issued for the company

Apiro Diagnostics Kft.

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

Intended purpose of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

The TPA is a ready to use reagent for in-vitro diagnostic professional use, intended for detection of tranexamic acid in citrated blood during viscoelastometry analysis.

The IN is a ready to use reagent for in-vitro diagnostic professional use, intended for detection of unfractionated heparin in citrated blood during viscoelastometry analysis.

The HI is a ready to use reagent for in-vitro diagnostic professional use, intended for confirmation of unfractionated heparin in citrated blood during viscoelastometry analysis.

The AP is a ready to use reagent for in-vitro diagnostic professional use, intended for examination of whole blood clot formation with fibrinolysis inhibition in citrated blood during viscoelastometry analysis.

The FIB is a ready to use reagent for in-vitro diagnostic professional use, intended for qualitative examination of the fibrinogen level in citrated blood during viscoelastometry analysis.

The RVV is a ready to use reagent for in-vitro diagnostic professional use, intended for detection of direct FXa antagonists in citrated blood during viscoelastometry analysis.

The EX is a ready to use reagent for in-vitro diagnostic professional use, intended for examination of the extrinsic coagulation system in citrated blood during viscoelastometry analysis.

The QC1 is a quality control material based on normal plasma for in-vitro diagnostic professional use, intended for internal quality control of reagents for viscoelastometry analysis.

The QC2 is a quality control material based on normal plasma with the addition of an anticoagulant for in-vitro diagnostic professional use, intended for internal quality control of reagents for viscoelastometry analysis.

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In Bratislava, Slovak Republic, 2026-01-13
Valid until 2030-10-07

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-007/A

issued for the company

Apiro Diagnostics Kft.

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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-IVDR/QS-007	07.10.2025	IVDR036_2024	Initially granted certification
01	**2025-IVDR/QS-007/A**	**13.01.2026**	**IVDR085_2025 IVDR086_2025 IVDR087_2025 IVDR088_2025 IVDR089_2025 IVDR090_2025 IVDR091_2025 IVDR092_2025**	**Certificate supplemented with the following trade names: IN, HI, AP, FIB, RVV, EX for Haemostasis reagents & QC1, QC2 for Control plasma for haemostasis.**

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In Bratislava, Slovak Republic, 2026-01-13
Valid until 2030-10-07