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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2025-IVDR/QS-005

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic
Manufacturing sites:
Křižíkova 188/68, 612 00 Brno, Czech Republic
Karásek 1767/1, 621 00 Brno, Czech Republic
SRN No.: CZ-MF-000001803

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:

Devices intended to be used for screening/ confirmation of specific disorders/ impairments (IVR 0601)
(detailed list is stated in the annex I)
Intended purpose: Annex II
IVD MD class B
(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.

Conditions for or limitations to the validity of the certificate: **N/A**

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 IVD MD Technical Documentation Assessment Report No. IVDR047_2024 from 16.05.2025, IVD MD Performance Evaluation Assessment Report No. IVDR047_2024 from 16.05.2025 and IVD MD Audit Report No. SK-0735/25-2 from 02.12.2025. 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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Valid from: **09.12.2025**
Valid until: **06.06.2028**
First issue: **11.06.2025**
Revision: **01**
History: **Annex III**

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

In Bratislava, Slovak Republic, 09.12.2025

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-005

issued for the company

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

In vitro diagnostic medical device	Brand Name	REF	Tests No.
Microblot-Array Liver profile	Microblot-Array Liver profile	LKMMA48	48
Microblot-Array Autoimmune gastroenteritis panel	**Microblot-Array Autoimmune gastroenteritis panel IgA**	**AIGAMA48**	**48**
	Microblot-Array Autoimmune gastroenteritis panel IgG	**AIGGMA48**	**48**
CLIA Beta 2 Glycoprotein	**CLIA Beta 2 Glycoprotein IgA**	**CL-BGA100**	**100**
	CLIA Beta 2 Glycoprotein IgG	**CL-BGG100**	**100**
	CLIA Beta 2 Glycoprotein IgM	**CL-BGM100**	**100**
CLIA Cardiolipin	**CLIA Cardiolipin IgA**	**CL-CLA100**	**100**
	CLIA Cardiolipin IgG	**CL-CLG100**	**100**
	CLIA Cardiolipin IgM	**CL-CLM100**	**100**
CLIA GAD65	**CLIA GAD65**	**CL-GAD100**	**100**
CLIA IA2	**CLIA IA2**	**CL-IA100**	**100**
CLIA C-peptide	**CLIA C-peptide**	**CL-CPT050**	**50**
CLIA Insulin	**CLIA Insulin**	**CL-INS050**	**50**

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 09.12.2025
Valid until 06.06.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-005

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Microblot-Array Liver profile:
The Microblot-Array assay is intended for the diagnosis of autoimmune diseases using IgG antibodies against 13 different antigens (LKM-1, LC-1, SLA/LP, Sp100, gp210, ASGPR, PML, Nup62, M2, 3E(BPO), OGDC-E2, PDC-E2 and Ro52) in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory.

Microblot-Array Autoimmune gastroenteritis panel IgA:
The Microblot-Array assay is intended for the diagnosis of autoimmune diseases of the gastrointestinal tract using IgA antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory.

Microblot-Array Autoimmune gastroenteritis panel IgG:
The Microblot-Array assay is intended for the diagnosis of autoimmune diseases of the gastrointestinal tract using IgG antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory.

CLIA Beta 2 Glycoprotein IgA:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgA antibodies to beta-2-glycoprotein in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Beta 2 Glycoprotein IgG:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgG antibodies to beta-2-glycoprotein in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
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In Bratislava, Slovak Republic, 09.12.2025
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Intended purpose of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

CLIA Beta 2 Glycoprotein IgM:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgM antibodies to beta-2-glycoprotein in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Cardiolipin IgA:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgA antibodies to cardiolipin in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Cardiolipin IgG:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgG antibodies to cardiolipin in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Cardiolipin IgM:
The chemiluminescence assay is intended for use as an aid in the diagnosis of antiphospholipid syndrome (APS) and other autoimmune diseases using IgM antibodies to cardiolipin in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA GAD65:
The chemiluminescence assay is intended for use as an aid in the diagnosis of diabetes mellitus type I. using IgG antibodies to GAD65 in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

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Katarína Tomin Srdošová, PhD.
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Intended purpose of in vitro diagnostic medical devices covered by the EU Quality Management System Certificate:

CLIA IA2:
The chemiluminescence assay is intended for use as an aid in the diagnosis of diabetes mellitus type I. using IgG antibodies to IA2 in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA C-peptide:
The chemiluminescence assay is intended for use as an aid in diagnosis of disorders of insulin production, including diabetes mellitus, by determining the presence and quantity of C-peptide in human serum, EDTA plasma and urine in the general population presenting with symptoms typical of disorders of insulin production. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Insulin:
The chemiluminescence assay is intended for use as an aid in diagnosis of disorders of insulin production, including diabetes mellitus, by determining the presence and quantity of insulin in human serum and EDTA plasma in the general population presenting with symptoms typical of disorders of insulin production. The quantitative automated assay is designed for professional use in a laboratory.

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 09.12.2025
Valid until 06.06.2028

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-005

issued for the company

TestLine Clinical Diagnostics s.r.o.

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Manufacturing sites:
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Karásek 1767/1, 621 00 Brno, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2025-IVDR/QS-005	11.06.2025	IVDR047-2024	Initially granted certification
01	**2025-IVDR/QS-005**	**09.12.2025**	**IVDR046_2024 IVDR078_2025 IVDR079_2025 IVDR080_2025 IVDR081_2025 IVDR082_2025 IVDR083_2025**	**Certificate supplemented: Addition of new in vitro diagnostic medical devices: Microblot-Array Autoimmune gastroenteritis panel CLIA Beta 2 Glycoprotein CLIA Cardiolipin CLIA GAD65 CLIA IA2 CLIA C-peptide CLIA Insulin**

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 09.12.2025
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