Manufacturer: **TestLine Clinical Diagnostics s.r.o.**

Krizikova 188/68, 612 00 Brno, Czech Republic

Notified Body: **3EC International a.s. (No. 2265)**

Hranicna 1728/18, 821 05 Bratislava, Slovakia

EU Certificates

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2023-IVDR/QS-001

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic
Manufacturing sites:
1. Křižíkova 188/68, 612 00 Brno, Czech Republic
2. 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:

INFECTIOUS DISEASES, In vitro diagnostic devices which require knowledge regarding immunoassays (EMDN W0105 + IVP 3007)
(detailed list is stated in 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.

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. IVDR008_2023 from 26.05.2023, IVD MD Performance Evaluation Assessment Report No. IVDR008_2023 from 26.05.2023 and IVD MD Audit Report No. SK-0735/25 from 10.06.2025. 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.

Valid from: **11.06.2025**
Valid until: **06.06.2028**
First issue: **06.06.2023**
Revision: **02**
History: **Annex III**

In Bratislava, Slovakia, 11.06.2025

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic

Manufacturing sites:

1. Křižíkova 188/68, 612 00 Brno, Czech Republic
2. Karásek 1767/1, 621 00 Brno, Czech Republic

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

REF	Trade Name
CMGMA48	Microblot-Array CMV IgG
CMMMA48	Microblot-Array CMV IgM
HSGMA48	Microblot-Array HSV 1+2 IgG
HSMMA48	Microblot-Array HSV 1+2 IgM
CL-PVG050	CLIA Parvovirus B19 IgG
CL-PVM050	CLIA Parvovirus B19 IgM
CL-HSVG100	CLIA HSV 1+2 IgG
CL-HSVM100	CLIA HSV 1+2 IgM
CL-VZVA100	CLIA VZV IgA
CL-VZVG100	CLIA VZV IgG
CL-VZVM100	CLIA VZV IgM
CL-TgA100	**CLIA Toxoplasma IgA**
CL-TgG100	**CLIA Toxoplasma IgG**
CL-TgM100	**CLIA Toxoplasma IgM**

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic

Manufacturing sites:

1. Křižíkova 188/68, 612 00 Brno, Czech Republic
2. Karásek 1767/1, 621 00 Brno, Czech Republic

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

Microblot-Array CMV IgG, ref. CMGMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of CMV infection 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. The assay is not intended to assess the suitability for transfusion, transplantation or cell administration.

Microblot-Array CMV IgM, ref. CMMMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of CMV infection using IgM 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. The assay is not intended to assess the suitability for transfusion, transplantation or cell administration.

Microblot-Array HSV 1+2 IgG, ref. HSGMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of HSV infection 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.

Microblot-Array HSV 1+2 IgM, ref. HSMMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of HSV infection using IgM 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 Parvovirus B19 IgG, ref. CL-PVG050, Intended purpose: The chemiluminescence assay is intended for the diagnosis of parvovirus B19 infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Parvovirus B19 IgM, ref. CL-PVM050, Intended purpose: The chemiluminescence assay is intended for the diagnosis of parvovirus B19 infection using IgM antibodies 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.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic

Manufacturing sites:

1. Křižíkova 188/68, 612 00 Brno, Czech Republic
2. Karásek 1767/1, 621 00 Brno, Czech Republic

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

CLIA HSV 1+2 IgG, ref. CL-HSVG100, Intended purpose: The chemiluminescence assay is intended for the diagnosis and screening of HSV infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA HSV 1+2 IgM, ref. CL-HSVM100, Intended purpose: The chemiluminescence assay is intended for the diagnosis of HSV infection using IgM antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA VZV IgA, ref. CL-VZVA100, Intended purpose: The chemiluminescence assay is intended for the diagnosis of VZV infection using IgA antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA VZV IgG, ref. CL-VZVG100, Intended purpose: The chemiluminescence assay is intended for the diagnosis, monitoring and screening of VZV infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA VZV IgM, ref. CL-VZVM100, Intended purpose: The chemiluminescence assay is intended for the diagnosis of VZV infection using IgM antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Toxoplasma IgA, ref. CL-TgA100, Intended purpose: The chemiluminescence assay is intended for the diagnosis and screening of Toxoplasma gondii infection using IgA antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Toxoplasma IgG, ref. CL-TgG100, Intended purpose: The chemiluminescence assay is intended for the diagnosis and screening of Toxoplasma gondii infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Toxoplasma IgM, ref. CL-TgM100, Intended purpose: The chemiluminescence assay is intended for the diagnosis and screening of Toxoplasma gondii infection using IgM antibodies 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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In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

Katarína Tomin Srdošová, PhD.
Director of NB 2265

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 188/68, 612 00 Brno, Czech Republic

Manufacturing sites:

1. Křižíkova 188/68, 612 00 Brno, Czech Republic
2. 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	2023-IVDR/QS-001	06.06.2023	IVDR008_2023 IVDR009_2023 IVDR010_2023	First issue
01	2023-IVDR/QS-001	01.10.2024	IVDR015_2024 IVDR016_2024	Scope extension for: CLIA HSV 1+2 IgG, CLIA HSV 1+2 IgM, CLIA VZV IgA, CLIA VZV IgG, CLIA VZV IgM
02	**2023-IVDR/QS-001**	**11.06.2025**	**IVDR045_2024**	**Scope extension for: CLIA Toxoplasma IgA, CLIA Toxoplasma IgG, CLIA Toxoplasma IgM**

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-001

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:
Křižíkova 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 to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging (IVR 0504) (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.

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. IVDR017_2024 from 20.03.2024, IVD MD Performance Evaluation Assessment Report No. IVDR017_2024 from 27.03.2024 and IVD MD Audit Report No. SK-0735-24/M from 03.04.2024. 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: **12.04.2024**
Valid until: **06.06.2028**
First issue: **12.04.2024**
Revision: **00**
History: **Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Ing. Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

REF	Trade Name
CL-TeTG100	CLIA Tetanus Toxoid IgG

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

CLIA Tetanus Toxoid IgG, ref. CL-TeTG100

Intended purpose: The chemiluminescence assay is intended for the monitoring of Tetanus Toxoid IgG antibodies 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.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

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	2024-IVDR/QS-001	12.04.2024	IVDR017_2024	Initially granted certification

Notified body · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-002

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:
Křižíkova 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 to detect the presence of, or exposure to an infectious agent including sexually transmitted agents (IVR 0503)
(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.

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. IVDR018_2024 from 28.03.2024, IVD MD Performance Evaluation Assessment Report No. IVDR018_2024 from 01.04.2024 and IVD MD Audit Report No. SK-0735-24/M from 03.04.2024. 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: **12.04.2024**
Valid until: **06.06.2028**
First issue: **12.04.2024**
Revision: **00**
History: **Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Ing. Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-002

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

REF	Trade Name
CL-MyA100	CLIA Mycoplasma IgA
CL-MyG100	CLIA Mycoplasma IgG
CL-MyM100	CLIA Mycoplasma IgM

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-002

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

CLIA Mycoplasma IgA, ref. CL-MyA100

Intended purpose: The chemiluminescence assay is intended for the diagnosis of *Mycoplasma pneumoniae* infection using IgA antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Mycoplasma IgG, ref: CL-MyG100

Intended purpose: The chemiluminescence assay is intended for the diagnosis of *Mycoplasma pneumoniae* infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Mycoplasma IgM, ref: CL-MyM100

Intended purpose: The chemiluminescence assay is intended for the diagnosis of *Mycoplasma pneumoniae* infection using IgM antibodies 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.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-IVDR/QS-002

issued for the company

TestLine Clinical Diagnostics s.r.o.

Registered place of business: Křižíkova 68, 612 00 Brno, Czech Republic

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

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	2024-IVDR/QS-002	12.04.2024	IVDR018_2024	Initially granted certification

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2025-IVDR/QS-003

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 to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging (IVR 0504)
(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. IVDR043_2024 from 21.05.2025, IVD MD Performance Evaluation Assessment Report No. IVDR043_2025 from 21.05.2025 and IVD MD Audit Report No. SK-0735-25 from 10.06.2025. 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.

Valid from: **11.06.2025**
Valid until: **06.06.2028**
First issue: **11.06.2025**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 11.06.2025

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-003

issued for the company

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

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

REF	Trade Name
CL-BCSFG50	CLIA Borrelia CSF IgG
CL-BCSFM50	CLIA Borrelia CSF IgM

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-003

issued for the company

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

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

The chemiluminescence assay is intended for the diagnosis and monitoring of *Borrelia burgdorferi* sensu lato infection using IgG antibodies in human cerebrospinal fluid, serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory. The results obtained by this assay can be used to calculate the antibody index, which serves as an indicator of intrathecal IgG antibody synthesis.

The chemiluminescence assay is intended for the diagnosis and monitoring of *Borrelia burgdorferi* sensu lato infection using IgM antibodies in human cerebrospinal fluid, serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory. The results obtained by this assay can be used to calculate the antibody index, which serves as an indicator of intrathecal IgM antibody synthesis.

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-003

issued for the company

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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2025-IVDR/QS-003	11.06.2025	IVDR043_2024	Initially granted certification

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2025-IVDR/QS-004

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:

In vitro kit intended for use in screening, diagnosis or staging of malignant tumors (IVR 0301) (detailed list is stated in 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.
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. IVDR044_2024 from 09.06.2025, IVD MD Performance Evaluation Assessment Report No. IVDR044_2024 from 09.06.2025 and IVD MD Audit Report No. SK-0735-25 from 10.06.2025. 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: **11.06.2025**
Valid until: **06.06.2028**
First issue: **11.06.2025**
Revision: **00**
History: **Annex III**

In Bratislava, Slovakia, 11.06.2025

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

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ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-004

issued for the company

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

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

REF	Trade Name
CL-CGA100	CLIA Chromogranin A

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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issued for the company

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

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

The Chromogranin A CLIA test kit is a chemiluminescent assay (CLIA) for detection and quantitation of chromogranin A in human serum or EDTA plasma. The results of the assay may be used as an aid in the diagnosis of chromogranin A secreting neuroendocrine tumours, such as carcinoids. The assay is intended for use in patients with signs and symptoms consistent for neuroendocrine tumours. The quantitative automated assay is designed for professional use in a laboratory.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-IVDR/QS-004

issued for the company

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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2025-IVDR/QS-004	11.06.2025	IVDR044_2024	Initially granted certification

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2025

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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

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

issued for the company

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

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**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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Director of NB 2265

In Bratislava, Slovak Republic, 09.12.2025
Valid until 06.06.2028

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

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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Karásek 1767/1, 621 00 Brno, Czech Republic

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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Karásek 1767/1, 621 00 Brno, Czech Republic

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.
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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**

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
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Valid until 06.06.2028

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