**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

# 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

# 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
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NB 2265
NOTIFIKOVANÁ OSOBA

**Katarína Tomin Srdošová, PhD.**
*Director of NB 2265*

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

# 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*

# 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<br>IVDR009_2023<br>IVDR010_2023 | First issue |
| 01 | 2023-IVDR/QS-001 | 01.10.2024 | IVDR015_2024<br>IVDR016_2024 | Scope extension for:<br>CLIA HSV 1+2 IgG,<br>CLIA HSV 1+2 IgM,<br>CLIA VZV IgA,<br>CLIA VZV IgG,<br>CLIA VZV IgM |
| **02** | **2023-IVDR/QS-001** | **11.06.2025** | **IVDR045_2024** | **Scope extension for:<br>CLIA Toxoplasma IgA,<br>CLIA Toxoplasma IgG,<br>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

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

# 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 |



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Katarína Tomin Srdošová, PhD.
*Director of NB2265*

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

# 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

# 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

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

# 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

# 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

# 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

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

# 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

# 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.



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**Katarína Tomin Srdošová, PhD.**
*Director of NB 2265*

In Bratislava, Slovakia, 11.06.2025
Valid until 06.06.2028

# 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

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

# 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

# ANNEX II 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

**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

# 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

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:

**In vitro diagnostic devices that require knowledge of immunological tests (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 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

# 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:**

| REF | Trade Name |
|---|---|
| LKMMA48 | Microblot-Array Liver profile |



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

# ANNEX II 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

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

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.



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

# ANNEX III 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

**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 |



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