

**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

## EC Certificates

| Products                     | Certificate No.   | Validity*  | Page |
|------------------------------|-------------------|------------|------|
| BlueBLOT-LINE Chlamydia      | 2021-IVD/QS-001/A | 31/12/2027 | 2    |
| Microblot-Array Chlamydia    | 2021-IVD/QS-002/A | 31/12/2027 | 4    |
| EIA CMV                      | 2021-IVD/QS-003/A | 31/12/2027 | 6    |
| EIA Chlamydia                | 2021-IVD/QS-004/A | 31/12/2027 | 9    |
| EIA Chlamydia pneumoniae     | 2021-IVD/QS-005/A | 31/12/2027 | 12   |
| EIA Chlamydia trachomatis    | 2021-IVD/QS-006/A | 31/12/2027 | 15   |
| EIA Chlamydia pneumoniae REC | 2021-IVD/QS-007/A | 31/12/2027 | 18   |
| EIA Rubella                  | 2021-IVD/QS-008/A | 31/12/2027 | 21   |
| EIA Toxoplasma               | 2021-IVD/QS-009/A | 31/12/2027 | 24   |
| BLOT-LINE Chlamydia          | 2021-IVD/QS-010/A | 31/12/2027 | 27   |
| BLOT-LINE CMV                | 2021-IVD/QS-013/A | 31/12/2027 | 30   |
| BLOT-LINE Toxoplasma         | 2021-IVD/QS-014/A | 31/12/2027 | 32   |
| CLIA Chlamydia pneumoniae    | 2022-IVD/QS-003   | 31/12/2027 | 34   |
| CLIA CMV                     | 2022-IVD/QS-004   | 31/12/2027 | 36   |
| CLIA Chlamydia trachomatis   | 2022-IVD/QS-005   | 31/12/2027 | 38   |
| CLIA Rubella                 | 2022-IVD/QS-006   | 31/12/2027 | 40   |

\*The validity date is based on confirmation from the Notified Body regarding the extension of the validity of the certificates.





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-001/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**BlueBLOT-LINE Chlamydia IgA**  
**BlueBLOT-LINE Chlamydia IgG**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižikova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-1/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.



  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-001



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-001/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-002/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**Microblot-Array Chlamydia IgA**  
**Microblot-Array Chlamydia IgG**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křížikova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-2/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-002



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-002/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-003/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA CMV IgA**  
**EIA CMV IgG**  
**EIA CMV IgM**

(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

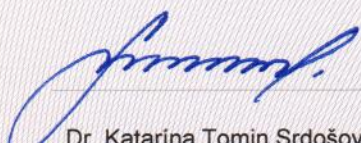
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-3/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-003



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-003/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-003/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

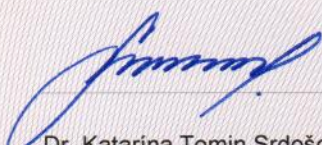
List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name | Variant          |
|-------------|------------------|
| EIA CMV IgA | EIA CMV IgA      |
|             | SmartEIA CMV IgA |
| EIA CMV IgG | EIA CMV IgG      |
|             | SmartEIA CMV IgG |
| EIA CMV IgM | EIA CMV IgM      |
|             | SmartEIA CMV IgM |

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At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025

  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-004/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA Chlamydia IgA**  
**EIA Chlamydia IgG**  
**EIA Chlamydia IgM**

(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-4/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-004



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-004/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-004/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name       | Variant                |
|-------------------|------------------------|
| EIA Chlamydia IgA | EIA Chlamydia IgA      |
|                   | SmartEIA Chlamydia IgA |
| EIA Chlamydia IgG | EIA Chlamydia IgG      |
|                   | SmartEIA Chlamydia IgG |
| EIA Chlamydia IgM | EIA Chlamydia IgM      |
|                   | SmartEIA Chlamydia IgM |

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Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-005/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA Chlamydia pneumoniae IgA**  
**EIA Chlamydia pneumoniae IgG**  
**EIA Chlamydia pneumoniae IgM**  
(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

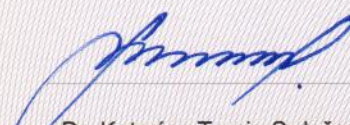
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-5/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-005



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-005/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-005/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name                  | Variant                           |
|------------------------------|-----------------------------------|
| EIA Chlamydia pneumoniae IgA | EIA Chlamydia pneumoniae IgA      |
|                              | SmartEIA Chlamydia pneumoniae IgA |
| EIA Chlamydia pneumoniae IgG | EIA Chlamydia pneumoniae IgG      |
|                              | SmartEIA Chlamydia pneumoniae IgG |
| EIA Chlamydia pneumoniae IgM | EIA Chlamydia pneumoniae IgM      |
|                              | SmartEIA Chlamydia pneumoniae IgM |

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Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-006/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA Chlamydia trachomatis IgA**  
**EIA Chlamydia trachomatis IgG**  
**EIA Chlamydia trachomatis IgM**  
(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

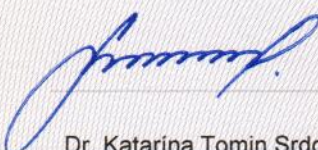
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-6/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-006



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-006/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-006/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name                   | Variant                            |
|-------------------------------|------------------------------------|
| EIA Chlamydia trachomatis IgA | EIA Chlamydia trachomatis IgA      |
|                               | SmartEIA Chlamydia trachomatis IgA |
| EIA Chlamydia trachomatis IgG | EIA Chlamydia trachomatis IgG      |
|                               | SmartEIA Chlamydia trachomatis IgG |
| EIA Chlamydia trachomatis IgM | EIA Chlamydia trachomatis IgM      |
|                               | SmartEIA Chlamydia trachomatis IgM |

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Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-007/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA Chlamydia pneumoniae REC IgA**  
**EIA Chlamydia pneumoniae REC IgG**  
(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

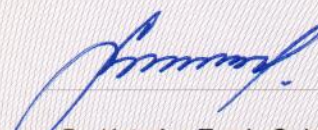
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-7/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-007



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-007/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-007/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name                      | Variant                               |
|----------------------------------|---------------------------------------|
| EIA Chlamydia pneumoniae REC IgA | EIA Chlamydia pneumoniae REC IgA      |
|                                  | SmartEIA Chlamydia pneumoniae REC IgA |
| EIA Chlamydia pneumoniae REC IgG | EIA Chlamydia pneumoniae REC IgG      |
|                                  | SmartEIA Chlamydia pneumoniae REC IgG |

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At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025

Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-008/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**EIA Rubella IgG**  
**EIA Rubella IgM**

(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křížikova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-8/2021.

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Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-008



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-008/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-008/A

issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name     | Variant              |
|-----------------|----------------------|
| EIA Rubella IgG | EIA Rubella IgG      |
|                 | SmartEIA Rubella IgG |
| EIA Rubella IgM | EIA Rubella IgM      |
|                 | SmartEIA Rubella IgM |

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Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-009/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

### EIA Toxoplasma

(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

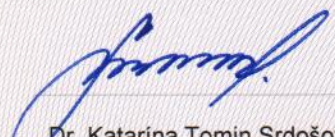
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-9/2021.

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Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-009



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-009/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-009/A

issued for the company

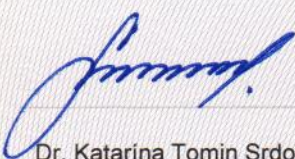
**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

| IVD MD Name        | Variant                 |
|--------------------|-------------------------|
| EIA Toxoplasma IgA | EIA Toxoplasma IgA      |
|                    | SmartEIA Toxoplasma IgA |
| EIA Toxoplasma IgE | EIA Toxoplasma IgE      |
|                    | SmartEIA Toxoplasma IgE |
| EIA Toxoplasma IgG | EIA Toxoplasma IgG      |
|                    | SmartEIA Toxoplasma IgG |
| EIA Toxoplasma IgM | EIA Toxoplasma IgM      |
|                    | SmartEIA Toxoplasma IgM |

Page 1 of 1



  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-010/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**BLOT-LINE Chlamydia**  
(for detailed list refer to Annex if it is necessary)

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-10/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-010



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-010/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





## ANNEX TO EC CERTIFICATE No. 2021-IVD/QS-010/A

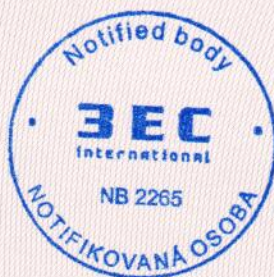
issued for the company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

### List of *in vitro* diagnostic medical devices covered by the EC Certificate:

|                                     |
|-------------------------------------|
| BLOT-LINE Chlamydia IgA             |
| BLOT-LINE Chlamydia IgG             |
| BLOT-LINE Chlamydia pneumoniae IgA  |
| BLOT-LINE Chlamydia pneumoniae IgG  |
| BLOT-LINE Chlamydia pneumoniae IgM  |
| BLOT-LINE Chlamydia trachomatis IgA |
| BLOT-LINE Chlamydia trachomatis IgG |

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At Bratislava, on May 23rd, 2022  
Valid until May 26th, 2025

Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-013/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**BLOT-LINE CMV IgG**  
**BLOT-LINE CMV IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

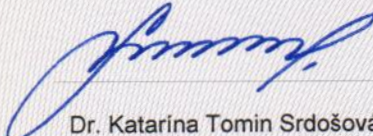
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-13/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-013



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-013/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2021-IVD/QS-014/A

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**BLOT-LINE Toxoplasma IgA**  
**BLOT-LINE Toxoplasma IgG**  
**BLOT-LINE Toxoplasma IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

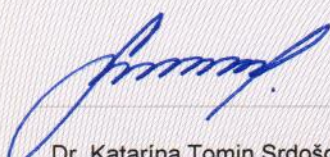
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT\_131 and the Final protocol No. 320065-14/2021.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 23rd, 2022  
This EC Certificate supersedes the EC Certificate No. 2021-IVD/QS-014



Certificate history:

| Revision | Date of issue | Application for Conformity Assessment of MD number | Description                                                                                                              |
|----------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 0        | 01.02.2021    | 320065                                             | First issue of the Certificate                                                                                           |
| A        | 23.05.2022    | 320065                                             | Issue of Certificate No. 2021-IVD/QS-014/A with extended validity until May 26th, 2025 based on Regulation (EU) 2022/112 |
|          |               |                                                    |                                                                                                                          |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2022-IVD/QS-003

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**CLIA Chlamydia pneumoniae IgA**  
**CLIA Chlamydia pneumoniae IgG**  
**CLIA Chlamydia pneumoniae IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižikova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 320070-320073 and the Final protocol No. 320071/2022.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup> 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 26th, 2022



Certificate history:

| Revision | Date of issue | Application for<br>Conformity<br>Assessment of IVD<br>MD number | Description                                       |
|----------|---------------|-----------------------------------------------------------------|---------------------------------------------------|
| 00       | 26.05.2022    | 320071                                                          | First issue of Certificate<br>No. 2022-IVD/QS-003 |
|          |               |                                                                 |                                                   |
|          |               |                                                                 |                                                   |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2022-IVD/QS-004

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**CLIA CMV IgA**  
**CLIA CMV IgG**  
**CLIA CMV IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 320070-320073 and the Final protocol No. 320070/2022.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup> 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarina Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 26th, 2022



Certificate history:

| Revision | Date of issue | Application for<br>Conformity<br>Assessment of IVD<br>MD number | Description                                       |
|----------|---------------|-----------------------------------------------------------------|---------------------------------------------------|
| 00       | 26.05.2022    | 320070                                                          | First issue of Certificate<br>No. 2022-IVD/QS-004 |
|          |               |                                                                 |                                                   |
|          |               |                                                                 |                                                   |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2022-IVD/QS-005

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**CLIA Chlamydia trachomatis IgA**  
**CLIA Chlamydia trachomatis IgG**  
**CLIA Chlamydia trachomatis IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

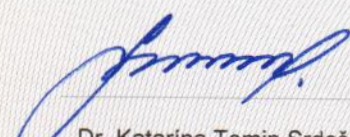
are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 320070-320073 and the Final protocol No. 320072/2022.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup> 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 26th, 2022



Certificate history:

| Revision | Date of issue | Application for<br>Conformity<br>Assessment of IVD<br>MD number | Description                                       |
|----------|---------------|-----------------------------------------------------------------|---------------------------------------------------|
| 00       | 26.05.2022    | 320072                                                          | First issue of Certificate<br>No. 2022-IVD/QS-005 |
|          |               |                                                                 |                                                   |
|          |               |                                                                 |                                                   |





3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia  
Notified Body No. 2265

## EC CERTIFICATE

No. 2022-IVD/QS-006

issued in compliance with Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices as amended, certifies that in vitro diagnostic medical devices according to Annex II, List B

**CLIA Rubella IgG**  
**CLIA Rubella IgM**

manufactured by company

**TestLine Clinical Diagnostics s.r.o.**  
Křižíkova 68, 612 00 Brno, Czech Republic

are manufactured under conditions fulfilling the quality system requirements of Annex IV, excluding (4 and 6), of the Directive 98/79/EC.

The Notified Body No. 2265 has performed an audit of the above products quality system and found that quality system meets the requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex IV, Section 5, of the Directive 98/79/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 320070-320073 and the Final protocol No. 320073/2022.

*This Certificate is issued under the following conditions:*

It applies only to the quality system maintained in the manufacture of the above referenced models of in vitro diagnostic medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26<sup>th</sup> 2025 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer.



  
Dr. Katarína Tomin Srdošová  
Responsible to act on behalf of NB 2265

At Bratislava, on May 26th, 2022



Certificate history:

| Revision | Date of issue | Application for<br>Conformity<br>Assessment of IVD<br>MD number | Description                                       |
|----------|---------------|-----------------------------------------------------------------|---------------------------------------------------|
| 00       | 26.05.2022    | 320073                                                          | First issue of Certificate<br>No. 2022-IVD/QS-006 |
|          |               |                                                                 |                                                   |
|          |               |                                                                 |                                                   |