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

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

3EC International

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.
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. 320065-1/2021.

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.

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

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-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

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international

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.
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. 320065-2/2021.

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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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

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international

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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

Notified body
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NB 2265
NOTIFIKOVANÁ OSOBA

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

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.

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

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

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international

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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

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.

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

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

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

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

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.
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. 320065-8/2021.

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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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.

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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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.

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

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

3EC International SKTC-113 3EC International SKTC-113 3EC International SKTC-113

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

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.

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

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.
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. 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 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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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 Conformity Assessment of IVD MD number	Description
00	26.05.2022	320071	First issue of Certificate 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 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.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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 Conformity Assessment of IVD MD number	Description
00	26.05.2022	320070	First issue of Certificate 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 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.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

At Bratislava, on May 26th, 2022

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Certificate history:

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

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international

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 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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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 Conformity Assessment of IVD MD number	Description
00	26.05.2022	320073	First issue of Certificate No. 2022-IVD/QS-006