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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-002

TestLine Clinical Diagnostics s.r.o.

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

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

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended confirms, that quality management system of in vitro diagnostic medical device:

Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents (IVR 0503)
(detailed list is stated in the annex I)

Intended purpose: Annex II
IVD MD class B
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR018_2024 from 28.03.2024, IVD MD Performance Evaluation Assessment Report No. IVDR018_2024 from 01.04.2024 and IVD MD Audit Report No. SK-0735-24/M from 03.04.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned in vitro diagnostic medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **12.04.2024**
Valid until: **06.06.2028**
First issue: **12.04.2024**
Revision: **00**
History: **Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 12.04.2024

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

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

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

CLIA Mycoplasma IgA, ref. CL-MyA100

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

CLIA Mycoplasma IgG, ref: CL-MyG100

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

CLIA Mycoplasma IgM, ref: CL-MyM100

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

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2024-IVDR/QS-002	12.04.2024	IVDR018_2024	Initially granted certification

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028