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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-001

TestLine Clinical Diagnostics s.r.o.

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

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

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

Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging (IVR 0504) (detailed list is stated in the annex I)

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

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

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

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR017_2024 from 20.03.2024, IVD MD Performance Evaluation Assessment Report No. IVDR017_2024 from 27.03.2024 and IVD MD Audit Report No. SK-0735-24/M from 03.04.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

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

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

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 12.04.2024

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

REF	Trade Name
CL-TeTG100	CLIA Tetanus Toxoid IgG

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

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

CLIA Tetanus Toxoid IgG, ref. CL-TeTG100

Intended purpose: The chemiluminescence assay is intended for the monitoring of Tetanus Toxoid IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

Křižíkova 68, 612 00 Brno, Czech Republic

Karásek 1767/1, 621 00 Brno, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2024-IVDR/QS-001	12.04.2024	IVDR017_2024	Initially granted certification

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 12.04.2024
Valid until 06.06.2028

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