3EC International

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2023-IVDR/QS-001

TestLine Clinical Diagnostics s.r.o.

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

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

INFECTIOUS DISEASES, In vitro diagnostic devices which require knowledge regarding immunoassays (EMDN W0105 + IVP 3007)
(detailed list is stated in Annex I)

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

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

Conditions for or limitations to the validity of the certificate: **N/A**

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

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR008_2023 from 26.05.2023, IVD MD Performance Evaluation Assessment Report No. IVDR008_2023 from 26.05.2023 and IVD MD Audit Report No. SK-0735-23 from 26.05.2023. 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: **06.06.2023**
Valid until: **06.06.2028**
First issue: **06.06.2023**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 06.06.2023

3EC International a.s.
Ing. Katarína Tomin Srdošová, PhD.
Ředitel NO2265

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

REF	Trade Name
CMGMA48	Microblot-Array CMV IgG
CMMMA48	Microblot-Array CMV IgM
HSGMA48	Microblot-Array HSV 1+2 IgG
HSMMA48	Microblot-Array HSV 1+2 IgM
CL-PVG050	CLIA Parvovirus B19 IgG
CL-PVM050	CLIA Parvovirus B19 IgM

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 06.06.2023
Valid until 06.06.2028

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

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Manufacturing sites:

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

Microblot-Array CMV IgG, ref. CMGMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of CMV infection using IgG antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory. The assay is not intended to assess the suitability for transfusion, transplantation or cell administration.

Microblot-Array CMV IgM, ref. CMMMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of CMV infection using IgM antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory. The assay is not intended to assess the suitability for transfusion, transplantation or cell administration.

Microblot-Array HSV 1+2 IgG, ref. HSGMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of HSV infection using IgG antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory.

Microblot-Array HSV 1+2 IgM, ref. HSMMA48, Intended purpose: The Microblot-Array assay is intended for the diagnosis of HSV infection using IgM antibodies in human serum or plasma in the general population. The qualitative, semi-quantitative and quantitative automated assay is designed for professional use in a laboratory.

CLIA Parvovirus B19 IgG, ref. CL-PVG050, Intended purpose: The chemiluminescence assay is intended for the diagnosis of parvovirus B19 infection using IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

CLIA Parvovirus B19 IgM, ref. CL-PVM050, Intended purpose: The chemiluminescence assay is intended for the diagnosis of parvovirus B19 infection using IgM antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 06.06.2023
Valid until 06.06.2028

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-IVDR/QS-001

issued for the company

TestLine Clinical Diagnostics s.r.o.

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

Manufacturing sites:

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2. Karásek 1767/1, 621 00 Brno, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of IVD MD number	Description
00	2023-IVDR/QS-001	06.06.2023	IVDR008_2023 IVDR009_2023 IVDR010_2023	First issue

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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 06.06.2023
Valid until 06.06.2028