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

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