3EC 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