TestLine Clinical Diagnostics s.r.o.
Křižíkova 188/68
612 00 Brno
Czech Republic

Attn. to: RNDr. Michal Beránek, Ph.D / executive manager

Our reference	***Contact person***	BRATISLAVA
MIT/2025/IVDR007/EN	Michal Tomin / +421 915 366 774	23.05.2025

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a. s.**, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

TestLine Clinical Diagnostics s.r.o..
Křižíkova 188/68
612 00 Brno
Czech Republic

SRN Number (if available): CZ-MF-000001803

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.
In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

• 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR

• For devices not requiring the involvement of a notified body under the IVDD**,** but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:

- o 31 December 2027, for class D devices;
- o 31 December 2028, for class C devices;
- o 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body,

Ing. Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Antibody test **Trade name:** **BlueBLOT-LINE Chlamydia** **Models:** BlueBLOT-LINE Chlamydia IgA BlueBLOT-LINE Chlamydia IgG **Basic UDI-DI:** IgA: 8595635306815DB IgG: 8595635306846DN	Class C	N/A	2021-IVD/QS-001/A NB2265
Antibody test **Trade name:** **BLOT-LINE Chlamydia** **Models:** BLOT-LINE Chlamydia IgA BLOT-LINE Chlamydia IgG BLOT-LINE Chlamydia trachomatis IgA BLOT-LINE Chlamydia trachomatis IgG **Basic UDI-DI:** IgA: 8595635304422C6 IgG: 8595635304439CP trachomatis IgA: 8595635304033BP trachomatis IgG: 8595635304040BL	Class C	N/A	2021-IVD/QS-010/A NB2265

Antibody test **Trade name:** **BLOT-LINE Chlamydia pneumoniae** **Models:** BLOT-LINE Chlamydia pneumoniae IgA BLOT-LINE Chlamydia pneumoniae IgG BLOT-LINE Chlamydia pneumoniae IgM **Basic UDI-DI:** IgA: 8595635304408CC IgG: 8595635304415C9 IgM: 8595635305184CL	Class B	N/A	2021-IVD/QS-010/A NB2265
Antibody test **Trade name:** **BLOT-LINE CMV** **Models:** BLOT-LINE CMV IgG BLOT-LINE CMV IgM **Basic UDI-DI:** IgG: 8595635309533DK IgM: 8595635309526DN	Class C	N/A	2021-IVD/QS-013/A NB2265
Antibody test **Trade name:** **BLOT-LINE Toxoplasma** **Models:** BLOT-LINE Toxoplasma IgA BLOT-LINE Toxoplasma IgG BLOT-LINE Toxoplasma IgM **Basic UDI-DI:** IgA: 8595635309595E9 IgG: 8595635309588EC IgM: 8595635309571DT	Class C	N/A	2021-IVD/QS-014/A NB2265
Antibody test **Trade name:** **CLIA Chlamydia pneumoniae** **Models:** CLIA Chlamydia pneumoniae IgA CLIA Chlamydia pneumoniae IgG CLIA Chlamydia pneumoniae IgM **Basic UDI-DI:** IgA: 8595635310164BN IgG: 8595635310171BK IgM: 8595635310188C4	Class B	N/A	2022-IVD/QS-003 NB2265
Antibody test **Trade name:** **CLIA CMV** **Models:** CLIA CMV IgA CLIA CMV IgG CLIA CMV IgM **Basic UDI-DI:** IgA: 8595635309946EG IgG: 8595635309953ED IgM: 8595635309960EA	Class C	N/A	2022-IVD/QS-004 NB2265

Antibody test **Trade name:** **CLIA Rubella** **Models:** CLIA Rubella IgG CLIA Rubella IgM **Basic UDI-DI:** IgG: 8595635310263BR IgM: 8595635310270BN	Class C	N/A	2022-IVD/QS-006 NB2265
Antibody test **Trade name:** **CLIA Chlamydia trachomatis** **Models:** CLIA Chlamydia trachomatis IgA CLIA Chlamydia trachomatis IgG CLIA Chlamydia trachomatis IgM **Basic UDI-DI:** IgA: 8595635310195BZ IgG: 8595635310201B3 IgM: 8595635310218BL	Class C	N/A	2022-IVD/QS-005 NB2265
Antibody test **Trade name:** **Microblot-Array Chlamydia** **Models:** Microblot-Array Chlamydia IgA Microblot-Array Chlamydia IgG **Basic UDI-DI:** IgA: 8595635306945DR IgG: 8595635306952DN	Class C	N/A	2021-IVD/QS-002/A NB2265
Antibody test **Trade name:** **EIA CMV / SmartEIA CMV** **Models:** EIA CMV IgA **/** SmartEIA CMV IgA EIA CMV IgG / SmartEIA CMV IgG EIA CMV IgM / SmartEIA CMV IgM **Basic UDI-DI:** EIA IgA: 8595635303210BE EIA IgG: 8595635302688CY EIA IgM: 8595635302695CV SmartEIA IgA: 8595635306266CW SmartEIA IgG: 8595635306280CQ SmartEIA IgM: 8595635306273CT	Class C	N/A	2021-IVD/QS-003/A NB2265
Antibody test **Trade name:** **EIA Chlamydia / SmartEIA Chlamydia** **Models:** EIA Chlamydia IgA / SmartEIA Chlamydia IgA EIA Chlamydia IgG / SmartEIA Chlamydia IgG EIA Chlamydia IgM / SmartEIA Chlamydia IgM **Basic UDI-DI:** EIA IgA: 8595635302855CT EIA IgG: 8595635302862CQ EIA IgM: 8595635302879D9 SmartEIA IgA: 8595635305764DC SmartEIA IgG: 8595635305771D9 SmartEIA IgM: 8595635305788DS	Class C	N/A	2021-IVD/QS-004/A NB2265

Antibody test **Trade name:** **EIA Chlamydia pneumoniae / SmartEIA Chlamydia pneumoniae** **Models:** EIA Chlamydia pneumoniae IgA / SmartEIA Chlamydia pneumoniae IgA EIA Chlamydia pneumoniae IgG / SmartEIA Chlamydia pneumoniae IgG EIA Chlamydia pneumoniae IgM / SmartEIA Chlamydia pneumoniae IgM **Basic UDI-DI:** EIA IgA: 8595635302886D6 EIA IgG: 8595635302893D3 EIA IgM: 8595635302909CR SmartEIA IgA: 8595635305795DP SmartEIA IgG: 8595635305801CR SmartEIA IgM: 8595635305818DA	Class B	N/A	2021-IVD/QS-005/A NB2265
Antibody test **Trade name:** **EIA Chlamydia trachomatis / SmartEIA Chlamydia trachomatis** **Models:** EIA Chlamydia trachomatis IgA / SmartEIA Chlamydia trachomatis IgA EIA Chlamydia trachomatis IgG / SmartEIA Chlamydia trachomatis IgG EIA Chlamydia trachomatis IgM / SmartEIA Chlamydia trachomatis IgM **Basic UDI-DI:** EIA IgA: 8595635302916CN EIA IgG: 8595635302923CK EIA IgM: 8595635302930CG SmartEIA IgA: 8595635305863DF SmartEIA IgG: 8595635305870DC SmartEIA IgM: 8595635305887DV	Class C	N/A	2021-IVD/QS-006/A NB2265
Antibody test **Trade name:** **EIA Chlamydia pneumoniae REC / SmartEIA Chlamydia pneumoniae REC** **Models:** EIA Chlamydia pneumoniae REC IgA / SmartEIA Chlamydia pneumoniae REC IgA EIA Chlamydia pneumoniae REC IgG / SmartEIA Chlamydia pneumoniae REC IgG **Basic UDI-DI:** EIA IgA: 8595635304460CE EIA IgG: 8595635304477CX SmartEIA IgA: 8595635305894DS SmartEIA IgG: 8595635305900CU	Class B	N/A	2021-IVD/QS-007/A NB2265

Antibody test **Trade name:** **EIA Rubella / SmartEIA Rubella** **Models:** EIA Rubella IgG / SmartEIA Rubella IgG EIA Rubella IgM / SmartEIA Rubella IgM **Basic UDI-DI:** EIA IgG: 8595635305016BW EIA IgM: 8595635305023BT SmartEIA IgG: 8595635306013BX SmartEIA IgM: 8595635306006C2	Class C	N/A	2021-IVD/QS-008/A NB2265
Antibody test **Trade name:** **EIA Toxoplasma / SmartEIA Toxoplasma** **Models:** EIA Toxoplasma IgA / SmartEIA Toxoplasma IgA EIA Toxoplasma IgE / SmartEIA Toxoplasma IgE EIA Toxoplasma IgG / SmartEIA Toxoplasma IgG EIA Toxoplasma IgM / SmartEIA Toxoplasma IgM **Basic UDI-DI:** EIA IgA: 8595635303043BK EIA IgE: 8595635303050BG EIA IgG: 8595635303067BZ EIA IgM: 8595635303074BW SmartEIA IgA: 8595635305856DJ Smart EIA IgE: 8595635305849DM SmartEIA IgG: 8595635305832D4 SmartEIA IgM: 8595635305825D7	Class C	N/A	2021-IVD/QS-009/A NB2265

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2025/05/23	MIT/2025/IVDR007/EN	Initial issue