Ecoli Dx, s.r.o.
Purkyňova 74/2
110 00 Praha
Czech Republic

Attn. to: Tomáš Hanzlík / CEO

Our reference	***Contact person***	BRATISLAVA
MIT/2026/IVDR014	Michal Tomin / +421 915 366 774	26.05.2026

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:

Ecoli Dx, s.r.o.
Purkyňova 74/2
110 00 Praha
Czech Republic

SRN Number (if available): CZ-MF-000023792

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issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a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,

3EC International a. s.
Hraničná 18, 821 05 Bratislava
Slovenská republika
IČO: 36 789 003
IČ DPH: SK2022390073

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
N/A	N/A	N/A	N/A

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
Trade name: eSens Neisseria gonorrhoeae QL PCR kit Model: ES3000A Basic UDI-DI: 859421198ES3000AD6	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Treponema pallidum QL PCR kit Model: ES3001A Basic UDI-DI: 859421198ES3001AD9	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Trichomonas vaginalis QL PCR kit Model: ES3002A Basic UDI-DI: 859421198ES3002ADC	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens Mycoplasma genitalium QL PCR kit Model: ES3003A Basic UDI-DI: 859421198ES3003ADF	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Mycoplasma hominis QL PCR kit Model: ES3004A Basic UDI-DI: 859421198ES3004ADJ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Gardnerella vaginalis QL PCR kit Model: ES3005A Basic UDI-DI: 859421198ES3005ADM	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Ureaplasma sp. QL PCR kit Model: ES3007A Basic UDI-DI: 859421198ES3007ADT	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens M.genitalium ML/FQ resistance QT PCR kit Model: ES3009B Basic UDI-DI: 859421198ES3009BE3	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Ureaplasma parvum/urealyticum QL PCR kit Model: ES3040A Basic UDI-DI: 859421198ES3040ADS	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Gardnerella vaginalis/Lactobacillus sp. QT PCR kit Model: ES3043A Basic UDI-DI: 859421198ES3043AE3	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Florocenosis/Bacterial Vaginosis QT PCR kit Model: ES3044A Basic UDI-DI: 859421198ES3044AE6	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Florocenosis/Mycoplasmas QT PCR kit Model: ES3045A Basic UDI-DI: 859421198ES3045AE9	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens Florocenosis/Aerobes QT PCR kit Model: ES3047A Basic UDI-DI: 859421198ES3047AEF	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name eSens Ureaplasma/M.genitalium/M.hominis QL PCR kit Model: ES3048A Basic UDI-DI: 859421198ES3048AEJ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens N.gonorrhoeae/M.genitalium/T.vaginalis QL PCR kit Model: ES3050A Basic UDI-DI: 859421198ES3050ADX	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HPV HR 14 screen/16,18,45 genotype QT PCR kit Model: ES3080A Basic UDI-DI: 859421198ES3080AEE	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HPV HR 14 genotype QT PCR kit Model: ES3081A Basic UDI-DI: 859421198ES3081AEH	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HPV HR 16/18 genotype QT PCR kit Model: ES3082A Basic UDI-DI: 859421198ES3082AEL	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HPV LR 6/11 genotype QL PCR kit Model: ES3090A Basic UDI-DI: 859421198ES3090AEK	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HAV QL PCR kit Model: ES3100B Basic UDI-DI: 859421198ES3100BDF	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HBV genotype QL PCR kit Model: ES3112B Basic UDI-DI: 859421198ES3112BDS	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens HCV genotype QL PCR kit Model: ES3122B Basic UDI-DI: 859421198ES3122BDX	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HSV 1/2 genotype QL PCR kit Model: ES3201A Basic UDI-DI: 859421198ES3201ADP	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens VZV QL PCR kit Model: ES3202B Basic UDI-DI: 859421198ES3202BDU	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens EBV QT PCR kit Model: ES3203A Basic UDI-DI: 859421198ES3203ADV	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HHV6 QT PCR kit Model: ES3206A Basic UDI-DI: 859421198ES3206AE6	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HHV7 QT PCR kit Model: ES3207A Basic UDI-DI: 859421198ES3207AE9	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens HHV8 QT PCR kit Model: ES3208A Basic UDI-DI: 859421198ES3208AEC	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens EBV/HHV6 QT PCR kit Model: ES3240A Basic UDI-DI: 859421198ES3240AE8	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens ARVI screen QL PCR kit Model: ES3304A Basic UDI-DI: 859421198ES3304AE7	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens Enterovirus QL PCR kit Model: ES3400B Basic UDI-DI: 859421198ES3400BE4	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Poliovirus QL PCR kit Model: ES3401B Basic UDI-DI: 859421198ES3401BE7	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens JCV/BKV QT PCR kit Model: ES3441A Basic UDI-DI: 859421198ES3441AER	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Parvovirus B19 QT PCR kit Model: ES3801B Basic UDI-DI: 859421198ES3801BF3	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Bordetella pertussis/bronchiseptica/parapertussis QL PCR kit Model: ES3300A Basic UDI-DI: 859421198ES3300ADT	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MTC QL PCR kit Model: ES3305B Basic UDI-DI: 859421198ES3305BEC	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MDR MTC QL PCR kit Model: ES3306B Basic UDI-DI: 859421198ES3306BEF	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Legionella pneumophila QT PCR kit Model: ES3307B Basic UDI-DI: 859421198ES3307BEJ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Corynebacterium diphtheriae/tox genes QL PCR kit Model: ES3308A Basic UDI-DI: 859421198ES3308AEK	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens Mycobacterium tuberculosis/bovis/BCG QL PCR kit Model: ES3309B Basic UDI-DI: 859421198ES3309BEQ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Listeria monocytogenes QT PCR kit Model: ES3402B Basic UDI-DI: 859421198ES3402BEA	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens N.meningitidis/H.influenzae/S.pneumoniae QL PCR kit Model: ES3440B Basic UDI-DI: 859421198ES3440BEQ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Acute intestinal infections QL PCR kit Model: ES3541B Basic UDI-DI: 859421198ES3541BF2	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Escherichioses QL PCR kit Model: ES3542B Basic UDI-DI: 859421198ES3542BF5	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Pneumocystis jirovecii QL PCR kit Model: ES3803B Basic UDI-DI: 859421198ES3803BF9	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Cryptococcus neoformans QL PCR kit Model: ES3804A Basic UDI-DI: 859421198ES3804AFA	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Leptospira QL PCR kit Model: ES3808B Basic UDI-DI: 859421198ES3808BFQ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens Streptococcus agalactiae QT PCR kit Model: ES3809A Basic UDI-DI: 859421198ES3809AFR	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Streptococcus pyogenes QT PCR kit Model: ES3810A Basic UDI-DI: 859421198ES3810AF3	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MRSA QT PCR kit Model: ES4300A Basic UDI-DI: 859421198ES4300AE6	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Dengue virus type QL PCR kit Model: ES3601B Basic UDI-DI: 859421198ES3601BEM	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens WNV QL PCR kit Model: ES3602B Basic UDI-DI: 859421198ES3602BEQ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Zika virus QL PCR kit Model: ES3605B Basic UDI-DI: 859421198ES3605BEZ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens Borrelia miyamotoi QL PCR kit Model: ES3701B Basic UDI-DI: 859421198ES3701BEU	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens TBEV/Borrelia/Anaplasma/Ehrlichia QL PCR kit Model: ES3740A Basic UDI-DI: 859421198ES3740AFB	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MDR MBL QL PCR kit Model: ES4301A Basic UDI-DI: 859421198ES4301AE9	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

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
Trade name: eSens MDR KPC/OXA QL PCR kit Model: ES4302A Basic UDI-DI: 859421198ES4302AEC	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MDR VRE QL PCR kit Model: ES4303A Basic UDI-DI: 859421198ES4303AEF	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive
Trade name: eSens MDR MCR-1 QL PCR kit Model: ES4304A Basic UDI-DI: 859421198ES4304AEJ	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directive

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2026/05/26	MIT/2026/IVDR014	Initial issue