In Prague, 10th December 2025

Subject: **eSens group D no longer to be supplied as IVDs**

Dear business partners,

We have thoroughly assessed the situation arising from the requirements set out in the legislation for continuing to place so-called legacy IVDDs (i.e., products that meet the requirements of Article 110 of the IVDR) on the market and have made the following decisions:

Unfortunately, we will no longer supply products from our portfolio that are classified in group D according to IVDR criteria (see attached list) as IVDs.

ES3301B	eSens Influenza virus A/H5N1 QL PCR kit
ES3312A	eSens NA SARS-CoV-2/SARS-CoV Multiplex
ES3603B	eSens CCHFV QL PCR kit
ES3604B	eSens EBOV Zaire QL PCR kit
ES3640B	eSens Plasmodium sp./falciparum/vivax QL PCR kit
ES3806B	eSens Bacillus anthracis QL PCR kit

With regard to other legacy IVDDs (i.e., those that will fall under Class B and Class C according to IVDR criteria), we have decided to take steps to meet the above requirements for their continued marketing within the maximum time limits allowed by the IVDR.

This announcement fully replaces previous announcement related to this matter (from the 16th October 2025).

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