NOEX Sp. z o.o. Sp. J.
Fabianowska Street 119-121
62-052 Komorniki, POLAND
+48 61 810 88 15/21
sales@noex.com.pl
www.noex.com.pl

Komorniki, 17 February 2026

STATEMENT

Noex Sp. z o.o. Sp. J., with its registered office at ul. Fabianowska 119-121, 62-052 Komorniki, Poland (hereinafter referred to as the "Manufacturer"), hereby declares that the in vitro diagnostic medical devices manufactured by the Manufacturer include the following devices:

Class A and Class A sterile, classified in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (IVDR).

Class A devices are directly subject to the requirements of Regulation (EU) 2017/746 from 26 May 2022 and are not covered by the transitional provisions set out in Article 110 of that Regulation.

With regard to sterile Class A devices, the transitional provisions set out in Article 110 of Regulation (EU) 2017/746, as amended by Regulation (EU) 2024/1860, apply. The manufacturer has assessed the conformity of these devices with the requirements applicable at the time of their placing on the market and has drawn up declarations of conformity in accordance with the applicable provisions.

In accordance with the transitional provisions, sterile class A devices may continue to be placed on the market or put into service until **31 December 2029**, provided that the applicable regulatory requirements are met, in particular:

- maintaining compliance with the provisions in force prior to the application of the IVDR;
- no significant changes to the design or intended use;

NOEX Sp. z o.o. Sp. J.
Fabianowska Street 119-121
62-052 Komorniki, POLAND
+48 61 810 88 15/21
sales@noex.com.pl
www.noex.com.pl

- no unacceptable risk to the health and safety of patients, users or other persons;
- implementation of a quality management system in accordance with the requirements of the IVDR;
- completion of the further conformity assessment procedure in accordance with the deadlines set out in Regulation (EU) 2017/746 and Regulation (EU) 2024/1860, to the extent applicable.

The manufacturer confirms that:

1. The devices comply with the applicable regulatory requirements;
2. No significant changes have been made to the design or intended use of the devices;
3. The devices do not pose an unacceptable risk to the health and safety of patients, users or other persons;
4. The manufacturer has implemented and maintains a quality management system in accordance with ISO 13485:2016.

The manufacturer's quality management system has been certified by an independent conformity assessment body and confirms the supervision of manufacturing processes and product quality within the scope of the certification.

Compliance with the above requirements is confirmed by the following attachments:

1. Product declarations of conformity;
2. ISO 13485:2016 quality management system certificate.

NOEX Sp. z o.o. Sp. J.
Fabianowska Street 119-121
62-052 Komorniki, POLAND
+48 61 810 88 15/21
sales@noex.com.pl
www.noex.com.pl

The manufacturer undertakes to comply with all applicable requirements related to the further assessment of product conformity in accordance with Regulation (EU) 2017/746, taking into account the deadlines and conditions specified in Regulation (EU) 2024/1860.

By accepting this offer, the Customer declares that he is familiar with all the characteristics of the product (including its legal status, physical features, specifications and intended use) and in this respect, he does not raise any objections. The acceptance of this offer results in the relations between the parties to the exclusion of Art. 556 - 576 of the Civil Code and art. 607 - 609 of the Civil Code. The acceptance of the offer is considered any statement made by the Customer, or persons acting on his behalf (employees, agents) - including the ones made via fax or e-mail - which shows a will to purchase goods from the Order Taker

En acceptant cette offre, le Client déclare qu'il connaît toutes les caractéristiques du produit (y compris son statut juridique, les caractéristiques physiques, les paramètres techniques et l'utilisation prévue) et à cet égard, il n'a pas soulevé d'objections. L'acceptation de cette offre se traduit dans les relations entre les parties par l'exclusion des articles 556 à 576 du Code civil et des articles 607 à 609 du Code civil. Comme l'acceptation de cette offre est considérée toute déclaration faite par le Client ou les personnes agissant en son nom (employés, agents) – y compris toute déclaration faite par fax ou e-mail - qui démontre la volonté d'acheter des produits du Vendeur

NOEX Sp. z o.o. Sp. J.

Fabianowska Street 119-121
62-052 Komorniki, POLAND

+48 61 810 88 15/21

sales@noex.com.pl
www.noex.com.pl

By accepting this offer, the Customer declares that he is familiar with all the characteristics of the product (including its legal status, physical features, specifications and intended use) and in this respect, he does not raise any objections. The acceptance of this offer results in the relations between the parties to the exclusion of Art. 556 - 576 of the Civil Code and art. 607 - 609 of the Civil Code. The acceptance of the offer is considered any statement made by the Customer, or persons acting on his behalf (employees, agents) - including the ones made via fax or e-mail - which shows a will to purchase goods from the Order Taker

En acceptant cette offre, le Client déclare qu'il connaît toutes les caractéristiques du produit (y compris son statut juridique, les caractéristiques physiques, les paramètres techniques et l'utilisation prévue) et à cet égard, il n'a pas soulevé d'objections. L'acceptation de cette offre se traduit dans les relations entre les parties par l'exclusion des articles 556 à 576 du Code civil et des articles 607 à 609 du Code civil. Comme l'acceptation de cette offre est considérée toute déclaration faite par le Client ou les personnes agissant en son nom (employés, agents) – y compris toute déclaration faite par fax ou e-mail - qui démontre la volonté d'acheter des produits du Vendeur