KABE LABORTECHNIK

Implementation of the EU IVD Regulation ((EU) 2017/746) on 05/26/2022

Dear valued customer,

With regard to the implementation and the associated conformity with the new EU Regulation for in vitro diagnostic devices as well as the availability of the IVD products supplied by us to you, there currently seems to be uncertainty among many users. Herewith we would like to inform you about the status of the implementation of the EU IVD Regulation in our company.

The EU IVD Regulation is due to come into force on 05/26/2022. A major innovation in this Regulation is a risk classification for in vitro diagnostic devices (see Annex VIII of the Regulation). For products that were lawfully placed on the market before 02/26/2022 on the basis of a valid certificate in accordance with the IVD Directive (98/79/EC) and a valid test certificate from a Notified Body, different transition and sales periods apply depending on the risk class.
The products we supply to you belong to the new risk classes A or A (sterile).

The sale of class A products is permitted up to a deadline of 05/26/2025 at the latest. From 05/26/2022 onwards, Class A devices that were placed on the market by us in a non-sterile state and already compliant with Directive 98/79/EC before 26.05.2022 with a valid test certificate from the notified body (so-called "old products" or "legacy devices") can be provided by us with evidence of their conformity in accordance with the EU-IVD Regulation. All applicable requirements of the EU-IVD Regulation for the devices are fulfilled. (see (EU) 2017/746, article 110 paragraph 4). Our test certificate according to ISO 13485 of the Notified Body is valid until 10/15/2024.

A transitional period for the sale of class A (sterile) devices applies up to a deadline of 26.05.2027. Until this date, devices that have been lawfully placed on the market with a valid test certificate from the notified body in accordance with Directive 98/79/EC may continue to be placed on the market.
In the future, a Notified Body must be involved in the conformity assessment with regard to the sterilization process and the maintenance of the sterile condition over the shelf life of these products. We are working intensively and continuously to ensure that we meet all the regulatory requirements of the new EU IVD Regulation within the applicable transition period.

The process of implementing the regulations according to the EU IVD Regulation is taken very seriously and systematically pursued by us. We currently comply with all regulatory requirements and can assure you that we will continue to supply you with legally compliant IVD products.

Mit freundlichen Grüßen

André Kolpe, Managing Director
Elsenroth, 05/25/2022