STATEMENT ON ORIGIN OF ADDITIVES

We declare under our sole responsibility that, according to the current information provided by our raw material supplier, the raw material used by us for the production of:

Reagent bottles with standard ground joint stopper, PP,

item no. 100394, 100494, 100594, 100694, 101594, 101694, 101794, 101894

was produced without actively use or intentionally incorporation of additives of animal origin (ADI).

Few additives derived from fatty acids of animal origin are still used. All suppliers of such additives guarantee that their manufacturing conditions exceed the requirements laid down in Regulation (EU) No 1069/2009, 142/2011 and "Note for Guidance EMA/410/01 (rev. 3)". Further, the plastic material is exposed to temperatures above 200 ºC for several minutes during the extrusion step in the plastic manufacturing process. Under the described conditions any virus, bacteria or substance causing immunological diseases (TSE; BSE, CJD) is destroyed.

Therefore the raw material used by us for the production of the reagent bottles with stopper should be considered safe with respect to BSE and TSE transmissions.

In addition, we have to point out that the products supported by VITLAB GmbH are laboratory articles of general use. The used raw material is not intended to be used for medical, pharmaceutical or healthcare applications and the raw material manufacturer do not support their use for such applications. This product is neither tested nor represented as suitable for medical or pharmaceutical uses by us.

All information is based on statements from our raw material suppliers, common experience or printed information and no responsibility is taken for the correctness of the provided information. Furthermore, we cannot exclude that a change in material may become necessary in the future. It is the user's responsibility to determine suitability of the product whether it may be used for the desired application or not.

Should you need any further information please do not hesitate to contact us again.

VITLAB GmbH

Grossostheim, 27. January 2025

Wolfgang Nicolaus	i.A. Dr. Stephan Schmidt
Geschäftsführer	Beauftragter Product Compliance
Managing Director	Regulatory Affairs

This letter has been typed and is valid without signature.