

Animal Origin and BSE/TSE Statement

This certificate applies to following products:

Optifit | Standard tips Safetyspace* | Filtered pipette tips

Manufacturer:

Sartorius Liquid Handling oy Tulppatie 1, 00880 Helsinki, Finland

Transmissible spongiform encephalopathies (TSEs) are chronic degenerative nervous diseases characterised by the accumulation of an abnormal isoform of a cellular glycoprotein known as prion protein. This abnormal isoform is considered to be the infective agent responsible for transmitting TSE. Interspecies transmission is possible under certain conditions. The most well-known TSEs are bovine spongiform encephalopathy (BSE) in cattle and Creutzfeldt-Jakob disease in humans.

Since there is a risk that TSEs may be transmitted through contact with infected tissue, the EU has established stringent legislation to prevent transmission of TSEs through animal-derived materials. Commission Regulation (EC) No 722/2012 and "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products" (EMA/410/01 rev. 3) set strict process conditions to render prions non-infective and to ensure the safety of animal-derived materials.

We hereby state that, having assessed raw materials of fluid-contact components of the above product families, no materials of animal origin are used.

The **Optifit** and **Safetyspace** products are safe to use without risk of BSE or TSE transmission.

Sartorius Liquid Handling oy Helsinki, January 21st 2025

-Signed by:

Kirsi Järvi

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Kirsi Järvi EHS Manager Sartorius Liquid Handling oy DocuSigned by:

Tuomas Huhmarniemi

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