

## ANIMAL ORIGIN AND BSE/TSE STATEMENT

This statement covers the following products:

Optifit | Standard tips Safetyspace\* | Filtered pipette tips

Manufacturer Sartorius Biohit Liquid Handling Oy

Laippatie 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.

Some polymers used in manufacturing of **Optifit** and **Safetyspace®** products may contain small amounts of animal-derived stearates. As the **Optifit** and **Safetyspace®** products are not medicinal products, the animal origin regulations apply to components in the fluid path only. We hereby state that, having assessed raw materials of fluid-contact components of the above product families, the processing conditions are in accordance with Section 3 of Annex I of Commission Regulation (EC) No 722/2012 and EMA/410/01 rev. 3. Assessments are based on supplier declarations. The **Optifit** and **Safetyspace®** products are safe to use without risk of BSE or TSE transmission.

Sartorius Biohit Liquid Handling Oy	
Helsinki, 22 <sup>nd</sup> January 2024	
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