

BSE-TSE STATEMENT

According to Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agent via Medicinal Products and Veterinary Medicinal Products (EMA/410/01 current revision)

3413 *tri-SODIUM CITRATE 2-HYDRATE parenteral GMP

We hereby confirm that the product referenced above does NOT contain substances of animal origin.

No substances of animal origin, or any of its derivatives, are intentionally added to the product during the manufacturing process. Furthermore, based on our current knowledge of the raw materials and our processes, no contamination with substances of animal origin is expected, therefore the product is not expected to contain BSE-TSE contamination either.

Esparreguera, August 23rd 2025

Laia Galitó
Regulatory Affairs Specialist

