

## NANOPARTICLES STATEMENT

According to 2011/696/EU Commission Recommendation.

### 3413 \*tri-SODIUM CITRATE 2-HYDRATE parenteral GMP

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We hereby confirm that the product referenced above does NOT contain nanoparticles, in accordance with the definition of 2011/696/EU Commission Recommendation.

No nanoparticles, or substances containing them, 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 nanoparticles is expected.

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Esparreguera, July 10th 2025

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Regulatory Affairs Specialist

