

NANOPARTICLES STATEMENT

According to 2011/696/EU Commission Recommendation.

3403 *EDTA, DISODIUM SALT 2-HYDRATE parenteral GMP

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.

Esparreguera, August 19th 2025

Laia Galitó
Regulatory Affairs Specialist

