

ETHYLENE OXIDE STATEMENT

3403 *EDTA, DISODIUM SALT 2-HYDRATE parenteral GMP

We hereby confirm that the product referenced above does NOT contain ethylene oxide.

No ethylene oxide, or substances containing ethylene oxide, 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 ethylene oxide is expected.

Esparreguera, August 19th 2025

Laia Galitó
Regulatory Affairs Specialist

