farma Qemical

quality chemicals

CMR STATEMENT

According to Regulation (EU) 109/2012

3417 *SODIUM FLUORIDE parenteral use GMP

We hereby confirm that the product referenced above is NOT classified as a CMR substance and does NOT contain any of the potential CMR substances currently listed in the Annex VI of the Regulation (EU) 1272/2008 and its amendment 1221/2015.

No CMR substances 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 CMR substances is expected.

Esparreguera, January 20th 2025

Laia Galitó
Regulatory Affairs Specialist