

## RESIDUAL SOLVENTS STATEMENT

According to EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

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

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We hereby confirm that the product referenced above is NOT manufactured using any of the solvents currently listed in the EU Directive 2009/32 modified by (EU) 2010/59 and CPMP/ICH/283/95 Q3C.

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Esparreguera, January 20th 2025

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