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Title: **Sterility of secondary packaging material/surface of primary packaging for Freeflex**

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Freeflex container is sterilized with both primary and secondary packaging material in an air/steam autoclave. The sterility of the solution (primary bag) and surface inside the overpouch (secondary packaging material) is assured by validated autoclave cyclus and sterility test according to Ph.Eur 2.6.1 or parametric release.

Sterility is assured where the secondary packaging material is undamaged and intact.

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References: S 12 11.00R

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Distribution: To whom it may concern

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