

EVAM® Mono-Chamber EVA TPN Bags

Integrity of the Nutrition Mixture

- The EVAM® ethylene vinyl acetate film used for the manufacturing of Sartorius Stedim Biotech bags is in conformance with ISO and USP Biocompatibility Standards and is covered by a Drug Master File (DMF) on record with the [FDA](#).
- EVAM film has an ultra low level of extractibles (USP <88> Plastic Class VI Test & ISO 10993-1) and contains no plasticizers.
- Full transparency is a major advantage for the visual inspection of both the empty bag and the solution.
- Each bag is air leak tested with filtered (0.2µm) compressed air (580g / cm2).

Quality Assurance

- Sartorius Stedim Biotech's Quality System is ISO 9001 and ISO 13485 (EN 46001) certified.
- CE Marking is in conformity with the 93/42/EEC Medical Device Directive.
- Sartorius Stedim Biotech is a registered device manufacturer with the FDA.

Exhaustive Range of Products

- Mono chamber bags are offered in nominal capacities ranging from 250ml up to 4L.
- Bags are designed for filling by gravity or by automated compounders.

