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Sartorius Stedim enhances single-use product portfolio

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Singapore: Biotechnology supplier company, Sartorius Stedim Biotech, has launched new range of single-use bags, under its Flexsafe range, that enables the implementation of single-use bioprocessing throughout all steps of drug manufacture using polyethylene film.

Flexsafe family addresses industry requirements for future-proof single-use manufacturing of commercial vaccines and drugs. Flexsafe is based on a multilayer, proprietary polyethylene (PE) film, called S80, and has been developed in close collaboration with resin and film suppliers. A standardized cell growth assay has been used to optimize film formulation, determine the operating ranges for extrusion, welding and gamma-irradiation processes and to establish specifications and process controls.

Flexsafe ensures reproducible cell growth behavior of sensitive cell lines. The optimization of the resin formulation, the complete control of raw materials, the extrusion process and the bag assembly guarantee lot-to-lot consistent cell growth performance.

Furthermore, batch-to-batch consistent extractables and leachables profiles support drug manufacturers throughout the entire lifecycle of modern biological treatments from clinical development to commercial supply many years after launch.

"Flexsafe represents a completely new generation of single-use bags. They offer our customers consistent cell growth as well as extraordinary robustness and flexibility. In addition a sustainable supply chain and consistent film throughout the entire manufacturing process is guaranteed. Every single one of these benefits sets a new benchmark. Being unique in all of them makes us very proud", stated Stefan Schlack, senior vice president-marketing and product management, Sartorius Stedim Biotech.