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Freudenberg Medical launches ISO Class 5 controlled cleanroom for sterile single-use assemblies

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New controlled cleaning and sterilisation service supports biopharma customers with ready-to-use single-use assemblies



Germany-based Freudenberg Medical, a global contract design and manufacturing partner to the medical device and biopharma industry, has announced the launch of CleanAssure, a new ISO Class 5 controlled cleanroom designed to deliver clean and sterile single-use assemblies for biopharmaceutical customers.

Freudenberg Medical manufactures silicone and thermoplastic elastomer (TPE) tubing for bioprocessing and critical fluid transfer. The company specialises in seamless, overmolded single-use assemblies used in vaccine production, cell cultivation, fluid transfer, and fill-finish operations.

The controlled cleanroom enables customers to receive ready-to-use washed, dried, and gamma sterilised single-use assemblies with the highest product quality, sterility, and process consistency.

Freudenberg's cleaning process uses ultrapure water and air, operating within tightly controlled ISO 5 conditions. The water is produced using a multi-stage filtration process resulting in high-purity water specifically suitable for pharmaceutical applications.

The controlled cleaning environment addresses challenges by reducing cross-contamination risk through tightly controlled ISO Class 5 processing; alleviating customer cleaning validation burden by delivering assemblies washed and sterilised under cGMP, validated conditions; minimising production downtime by removing cleaning as a process step; and supporting a consistent, reliable supply of high-quality single-use assemblies.