Microsart® for Sterility Assurance of Single Use Systems(SUS)

The Company is dedicated to the production of single-use bioprocessing bags and fluid management technologies, which are essential for the cultivation and processing of cell cultures in the biopharmaceutical industry. These products are integral to the production of vaccines, monoclonal antibodies, and other biologic drugs, supporting the industry's need for sterile, efficient, and scalable solutions.

Challenge

- Validation of the sterilization process according to ISO 11137
- SUS are described in EU GMP Annex 1 and chapter 8.134 requires they be validated. The Company shall demonstrate the evidence of sterilization of each unit, as part of pharmaceutical manufacturer's risk assessment and contamination control strategy
- Maintenance of sterility should be repeated routinely to demonstrate the effectiveness of the sterilization dose over time

The Solution

- All-in-one Microsart® filtration system, including e.jet pump, manifold and sterile, ready-to-use filtration units (0.45 µm gridded membranes, filter base and funnel)
- Microsart®@filter filtration units for bioburden validation from unirradiated representative products acc. to ISO 11737-1
- Microsart®@filter filtration units for sterility testing with the verification dose, producing a worst-case SAL 10-1 , followed by 14 days of incubation

For more information, visit www.sartorius.com

The Value

- Confidence in assessing the minimum dose granting a sterility assurance level (SAL) of 10-6
- Minimized risk of cross-contamination with a criteria of not more than 1 positive
- Microsart®@e.jet vacuum pump avoids excessive backpressures as recommended in ISO 11737-1 chapter B.4.2.2

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